

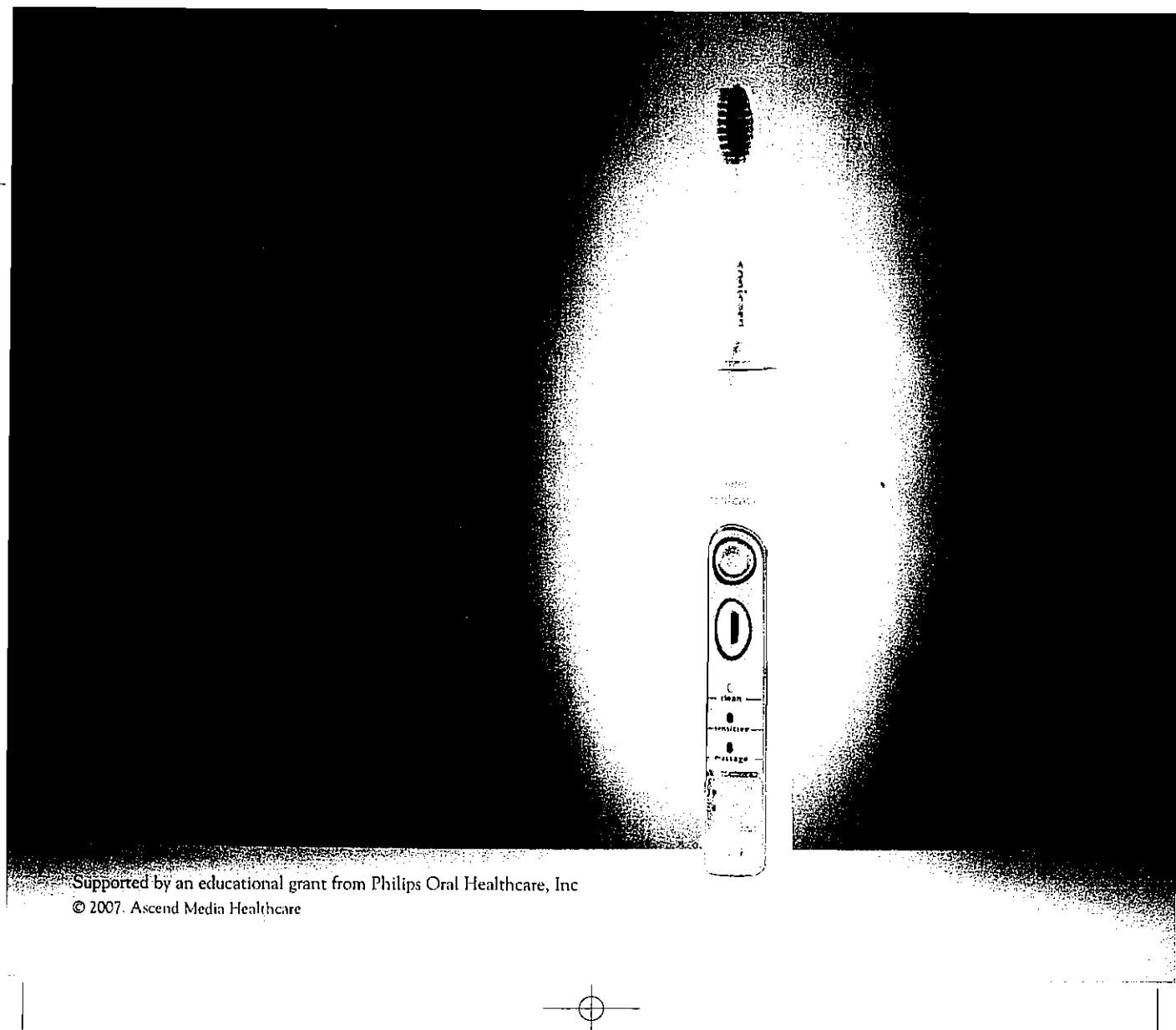
# **Exhibit A**

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A Supplement to  
**Compendium**  
of Continuing Education in Dentistry®

REVIEW OF KEY CLINICAL RESEARCH ON THE NEW  
Philips Sonicare FlexCare



Supported by an educational grant from Philips Oral Healthcare, Inc  
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# A Supplement to **Compendium** of Continuing Education in Dentistry®

Dear Colleague:

One of the most important findings of the past 3 decades is that more Americans are keeping their natural teeth past age 50 than ever before. This improvement in natural tooth retention has been noted in every census starting in 1970. It is a compliment to the dental profession, which has been teaching prevention and preservation of natural dentition. With an aging population that is retaining their teeth, more responsibility is placed on the patient to be a cotherapist in practicing good oral hygiene. The need to reduce biofilm and reduce the risk for dental caries and periodontal disease becomes a team effort involving the patient working with the dental team.

The need to maintain oral health is greater than ever since recent research has shown a connection between periodontal disease and diabetes, cardiovascular disease, and preterm low birthweight. The exact cause and effect relationships are still being investigated, but more and more data emphasize that having a healthy mouth is important to preserving systemic health. Technology that makes it possible for patients to be more effective in their personal oral hygiene is welcomed by the dental profession and the lay community.

This special supplement of the *Compendium* describes new research that makes the practice of good oral hygiene easier than in the past because of the development of a new instrument for home use. The more efficient we are in removing biofilm, the more effective we will be in improving oral health.

Ascend Dental Media is grateful to Philips Sonicare for the educational grant that made this supplement possible.



Sincerely,

D. Walter Cohen, DDS  
Editor-in-Chief



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# A Supplement to Compendium of Continuing Education in Dentistry\*

Dear Colleague:

The way dental professionals and the public view oral health and oral hygiene has changed significantly in recent years. The biofilm nature of plaque and its role in disease have been accepted and understood. Knowledge about the relationship between periodontal disease and systemic health has been widely disseminated. Most individuals are now aware that periodontitis may significantly enhance risk for cardiovascular disease, diabetic complications, and preterm low-birth-weight infants. There is an increasing focus on the importance of meticulous daily oral hygiene not only as a means of enhancing oral health and well-being, but also for prevention of potentially serious systemic diseases and conditions.

Most patients have a strong desire to practice excellent oral hygiene, but many continue to find it to be a difficult, burdensome, and uncomfortable task. Their efforts are compromised by hard-to-reach, inaccessible areas and, in some cases, by inadequate skill, poor motivation, and lack of compliance. The new Sonicare toothbrush, FlexCare, addresses many of these difficult issues.

Over the past 15 years, Sonicare has become a driving force in oral healthcare known for its technological innovations. FlexCare is an innovative standout even among its Sonicare predecessors. While FlexCare is documented to be highly effective at plaque removal, especially in hard-to-reach areas, its greatest distinction is the numerous design and functional features that enhance user satisfaction, convenience, comfort, and, ultimately, compliance. For example, one of the 3 brushing modes is sure to please any user, even those with sensitive teeth and gums. The handle is smaller and lighter, and vibrations are isolated from the handle of the user. The brush head is compact and the bristles are designed for greater comfort and tooth/tissue contact. Brushing effectiveness is less dependent on technique. The brush head snaps on and off and it can be sanitized by ultraviolet light treatment between brushings.

The data presented in the articles in this supplement to the *Compendium* document the features of FlexCare that make it "the best Sonicare ever."



Sincerely,

Roy C. Page, DDS, PhD



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# A New Generation of Sonicare Power Toothbrushes— The FlexCare Series

## Abstract

Using a power toothbrush is an excellent way to improve oral hygiene, with the ultimate goal to achieve optimal oral health. The Sonicare FlexCare series represents the third generation of Sonicare power toothbrushes. This article briefly describes the history of Sonicare power toothbrushes and the major differences between FlexCare and its predecessor models, Elite and Advance. Special attention is paid to the new ProResults brush head that features radial bristle trimming and tufting and the highly innovative drive system. The characteristics of the novel brushing modes and routines are explained, and the unique integrated brush head sanitizer is introduced.



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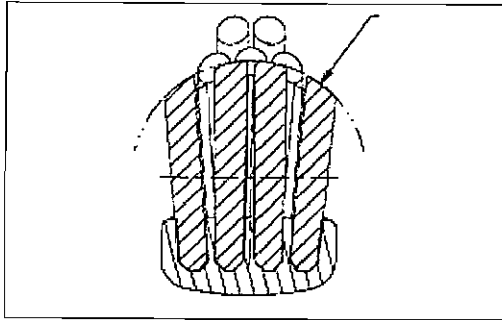
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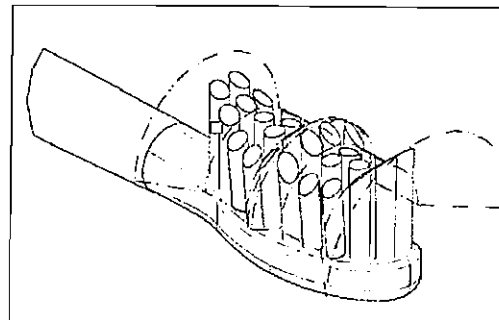
When the first Sonicare<sup>®</sup> was presented at the annual meeting of the American Academy of Periodontology 15 years ago, dental professionals welcomed the revolutionary power toothbrush with enthusiasm. The patented core technology<sup>1</sup> combined mechanical plaque removal with fluid dynamics generated by high-speed bristle motion for an improved cleaning and unique user experience. The first Sonicare, later dubbed Advance, was a landmark development in oral healthcare. Without any major modification, it represented the Sonicare brand for an entire decade. The Sonicare user community grew rapidly, and, with growth, the desire for an improved toothbrush with a new design and features was clear.

The second-generation Sonicare, named Elite for its superior performance and high-end market position, was presented in 2002. Needless to say, the patented sonic technology was preserved. But Elite exhibited numerous features that differentiated it from its predecessor. Most important was a new brush head with a bristle trim that closely fit the contour of the dentition. The slim shaft of the brush head was slightly angled and provided better access to hard-to-reach areas of the dentition. This was further supported by the oscillating, twisting rotation of the brush head that generated the characteristic sweeping bristle motion. Finally, the redesigned brush handle was smaller and lighter, featuring a battery charge indicator and a button that allowed toggling between high and low speeds. Clinical studies<sup>2-6</sup> confirmed the superiority of Elite and that the modifications represented significant improvements.

<sup>1</sup>Philips Oral Healthcare, Inc, Snoqualmie, WA.



**Figure 1**—Cross-section of the new ProResults brush head illustrating the novel radial trim. The crossing of the 2 perpendicular hairlines indicates the center of bristle trim



**Figure 2**—The lateral-oblique view reveals the 3-dimensional surface contour of the bristle tips

Even before launching Elite, the Philips Oral Healthcare management team decided that it should not take another 10 years until the introduction of the third Sonicare generation. A project team composed of designers, engineers, clinicians, and marketing specialists was created to develop the new Sonicare platform. Their objective was to develop a high-end product to meet the needs of a greater variety of users, reflecting the now-global outreach of the company. The updated toothbrush design was to be smaller, more effective in plaque removal, and incorporate other improvements. The patented core technology,<sup>1</sup> including high bristle tip amplitude at high frequency, remains the backbone of this new toothbrush generation. The objectives of this article are to review the unique features of this new sonic power toothbrush, the Sonicare FlexCare, and introduce the clinical and laboratory studies that provide evidence of its improved design and efficacy over previous models.

#### ProResults Brush Head

The ProResults brush head has a number of changes compared with the original Sonicare Elite brush head. Most obvious, it no longer includes components of the motor, which are now housed in the handle. This makes ProResults easier to clean, lighter, and smaller than previous Sonicare brush heads. The design also permitted increasing the length of the shaft. Now its useful length exceeds Oral-B's FlossAction brush head by one-half inch. As a result, it is far easier to clean hard-to-reach posterior tooth surfaces. A clinical study conducted by Schaeken and colleagues<sup>7</sup> in Nijmegen, the Netherlands, compared the plaque removal efficacy of the FlexCare and Oral-B Triumph<sup>®</sup> power toothbrushes. The results of the randomized clinical trial showed

greater reduction in plaque scores for the FlexCare.<sup>7</sup>

#### Radial Tufting and Trimming

While the bristling has retained the principal characteristics of the Sonicare Elite brush head, such as its double-scallop pattern that fits the natural outline of the dentition and the unique combination of soft, extra-soft, and ultra-soft end-rounded filaments, the ProResults brush head has been improved to deliver the best overall performance for the typical sweeping brush head motion.

This was achieved through radial tufting and trimming to enhance the position and contour of the bristle field. Radial tufting was created by rotating the outer tufts laterally by 5 degrees on each side (Figure 1). As a consequence, the brush profile is now defined with respect to the center of the brush head motion.

Radial trimming was achieved by adding a third dimension to the trim profile where Elite was essentially 2 dimensional. Because of radial trimming and tufting, any accessible tooth surface is cleaned by more bristles than with a flat, trimmed bristle surface (Figure 2). In addition to trimming and tufting, details of brush design, varying trim lengths, and filament selection were examined using numerous sequences of computer-assisted computations, as well as laboratory and clinical studies, to determine the best radial design.

Clinically, the advantage of the radial configuration is reducing the user's sensitivity to the orientation of the brush head in the mouth. This delivers more consistent cleaning performance with less reliance on the brushing technique. The outside rows of bristles, which are angled slightly lateral, further widen the available contact area. Also, in this new arrangement, the bristles are able to move more freely along the surface of the tooth.

<sup>1</sup>Proctor & Gamble Co; Cincinnati, OH.

Figure 3—FlexCare handle and ProResults brush head. The resonator with the revolutionary nodal mount is located in the anterior third of the handle

#### *Improved Plaque Removal and Reduced Gingival Inflammation*

As a result of these major improvements, the FlexCare toothbrush equipped with the ProResults brush head performed better than Sonicare Elite in plaque removal efficacy in a randomized clinical trial conducted by an independent clinical research organization in the United States, University Park Research Center in Fort Wayne, Indiana.<sup>8</sup> The results of this comparative study by Milleman and colleagues<sup>8</sup> show superior plaque removal efficacy for FlexCare overall and also in subregions of the dentition.

Comparably, in a study conducted at 4-Front Research in Cheshire, United Kingdom, on subjects exhibiting inoderate levels of plaque-induced gingival inflammation, FlexCare users exhibited a greater decrease in gingival bleeding than those assigned to a manual toothbrush.<sup>9</sup>

#### *New Handle*

Feedback from both consumers and professionals indicated that the Sonicare handle design could be improved. Only a completely new architecture of the handle, including the interface with the brush head, could address the issues that were raised. It was clear from the beginning that the recommended improvements required a new, smaller, and more sophisticated drive system.

#### *Motor Components*

The new FlexCare drive train uses advanced, innovative technology. In contrast to previous Sonicare generations, all components of the motor are in the handle (Figure 3) and the main resonator is mounted to the handle at its midpoint. In this configuration, the distal ends of the resonator rotate in opposite directions, working against each other. The primary benefit of this patented technology<sup>10</sup> is that it isolates motor vibrations from the hand of the user resulting in a more pleasant experience.

#### *Less Performance Variation*

A second improvement is that the FlexCare is less susceptible to performance variation due to changes in user grip strength. This characteristic is unique to resonant drive systems, like those used in all Sonicare products. In a traditionally mounted system like the one used in the Elite or Advance, the housing is part of the resonant system. As a result, when the user changes grip firmness during toothbrushing, the brush head amplitude also changes. Due to the innovative nodal mount of the resonator, this effect is not present in the new FlexCare, resulting in a more consistent brushing performance.

#### *Comparable Motor and Toothbrush Frequency*

A third enhancement is in the motor, which

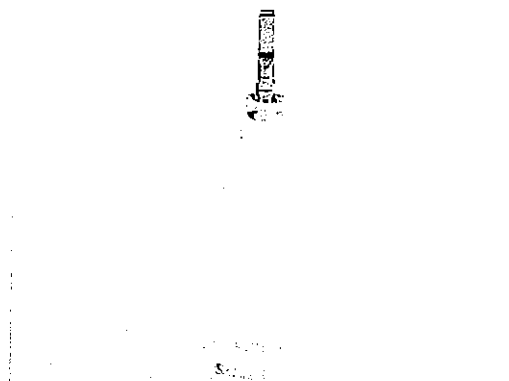


Figure 4—The new interface connecting the ProResults brush head and the FlexCare handle

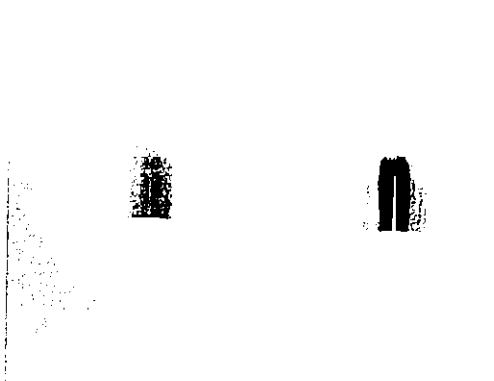


Figure 5—Comparison view of the brush head volume reduction between FlexCare and Elite

retains the optimized operating frequency at 260 Hz. During toothbrushing, the drive system's resonant frequency and impedance closely follow the changing load introduced by the brushing action. For example, when the user applies more force to the toothbrush, the drive system will respond so that the amplitude of the brush head motion will not change. This, in turn, means the cleaning power of the toothbrush is maintained at the same optimum level. The response is characteristic of the combination of the resonant driving system and how it is operated, and is not typically found in more traditional mechanical systems. As in previous Sonicare power toothbrushes, the FlexCare provides protection against brushing forces that might damage oral tissues. Information on the gentleness of FlexCare is summarized in an article by de Jager and colleagues.<sup>11</sup> The results from in vitro studies conducted at 3 independent research laboratories show that FlexCare is gentle on dentin, restorative and implant materials, and orthodontic brackets.

#### *Simplified Brush Head-Handle Interface*

All components of the new drive system are now integrated in the toothbrush handle. The brush head-handle interface has been greatly simplified (Figure 4) to make cleaning and changing brush heads very easy, with just a simple pull and push action. When testing the new feature with consumers, "brush head attachment and detachment" scored very high, and significantly better than Sonicare Elite, in a recently conducted consumer acceptance study among typical users of power toothbrushes (data on file).

The handle of the new FlexCare toothbrush exhibits additional new features that will make the product even more user friendly. The handle volume was cut by 30% (Figure 5) and given a unique curved "waist" design making it easier to grip and maneuver. The no-slip surfaces introduced with the Elite models have been retained to ensure it is easy to hold and handle firmly.

#### *Modes and Routines*

Ethnographic research conducted in users of power toothbrushes indicates an interest in oral hygiene procedures that meet individual preferences. While most persons brush their teeth twice per day for 2 minutes each time, many brush longer in the evening when they have more time than in the morning. Some people may want their gums massaged in addition to a deeper cleaning of their teeth. Other individuals like the vigorous cleaning action of the standard brushing mode and have no interest in alternatives. In response

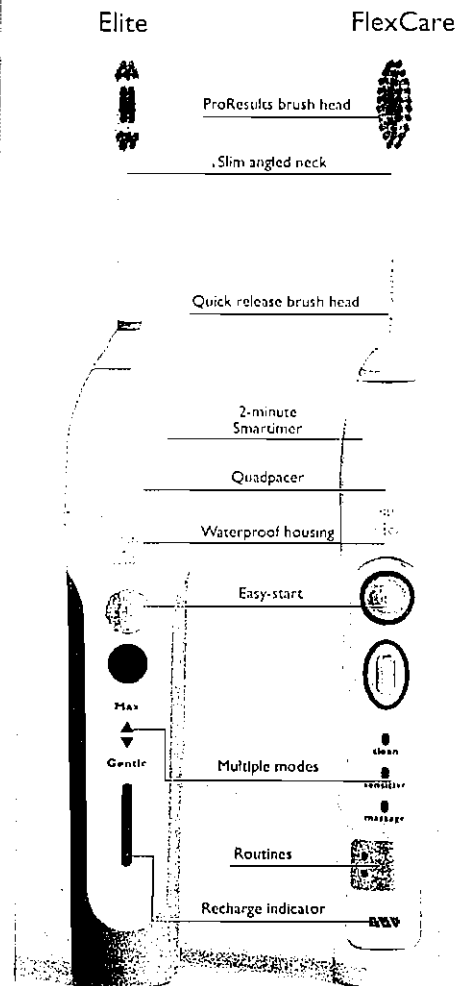


Figure 6—Anterior view comparison of design features of FlexCare and Elite

to this variety of needs, the FlexCare features several brushing modes and routines.

#### *Modes*

A mode is a combination of bristle frequency and amplitude that results in a characteristic brush head motion. FlexCare users can select among 3 brushing modes—clean, sensitive, and massage—that offer a setting for almost everyone that will improve their brushing experience and promote better compliance. A mode is selected simply by navigating with the second button on the FlexCare handle (Figure 6), where an indicator light clearly displays the selected setting. All 3 options include the Smartimer, which controls the amount of brushing time at the dental professional recommended 2 min-

utes, and Quadpacer, which prompts the user every 30 seconds to brush each quadrant.

**Clean.** The clean mode is similar to the proven patented combination of bristle amplitude and frequency previously applied in Sonicare Advance and Elite. This is the default mode and offers maximum efficacy for clean teeth and healthy gums. All clinical studies in this supplement were conducted with FlexCare in clean mode.

**Sensitive.** Dentin sensitivity is common today and is especially prevalent in patients with periodontitis or after periodontal treatment.<sup>12</sup> The sensitive mode is programmed to provide a gentler bristle action. The setting uses decreased bristle amplitude, but maintains the default bristle frequency range. This mode is similar to the gentle setting of the Sonicare Elite 9500 Custom Care System. It can be used by those with sensitive teeth or gums who still want the benefit of the Sonicare brushing action.

**Massage.** The massage mode is a new setting, programmed to stimulate the gums using an invigorating pulsing action. The 2-minute setting delivers episodes of bristle motion at varying amplitude and frequency. This option offers an even more refreshing brushing experience.

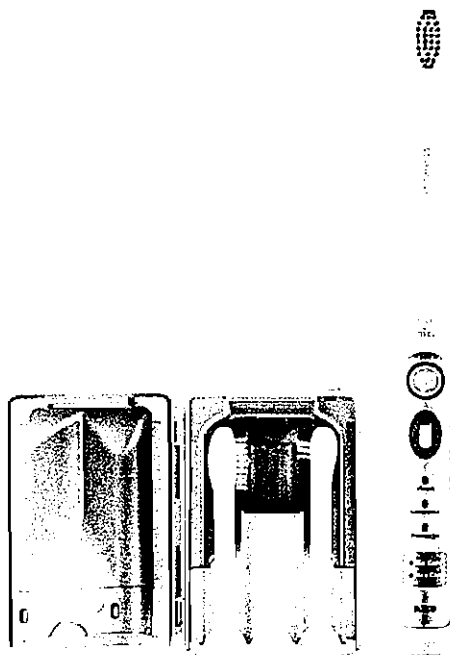


Figure 7—Brush head sanitizer available with some FlexCare models

## Routines

Brushing routines are an innovative new offering, exclusive to FlexCare. A routine is defined as a timed sequence of modes. Brushing routines were developed to accommodate the personal oral care habits of an increasingly diverse community of power toothbrush users. Ethnography research among Sonicare users shows that many would like to adjust their toothbrushing habits to fit better within their daily schedules. In response to this widespread request, FlexCare offers 2 brushing routines in addition to the default 2-minute setting.

**1 Minute.** The Go Care routine allows the user to get an effective yet short toothbrushing. The 1-minute brush head action is delivered at default amplitude and frequency. The Quadpacer 15-second interval timer encourages the user to brush each quadrant equally thoroughly. The Go Care routine is a way to benefit users with time restrictions, for example in the morning, who return for a full 2-minute brushing in the evening. Clinical research has shown that the Go Care routine removed significantly more plaque than a manual toothbrush when used for 1 minute (data on file).

**3 Minutes.** As an alternative, FlexCare users can choose the MaxCare routine, a sequence of 30 seconds of clean mode followed by 15 seconds of massage mode. The sequence is repeated 4 times for a total of 3 minutes of brushing time. MaxCare provides the most complete Sonicare cleaning.

All the performance improvements described above are based on well-established principles of sonic brushing, most importantly the patented sonic brush head motion.<sup>1</sup> Like other Sonicare toothbrushes, FlexCare uses sweeping, side-to-side oscillation optimized at 260 Hz to gain the unique advantage of high-speed bristle activity that supports the removal of plaque, especially in hard-to-reach areas.

## Biofilm Removal

The new FlexCare also removed more in vitro biofilm than another leading power toothbrush with rotating-oscillating brush head motion,<sup>13</sup> confirming results previously achieved using the Sonicare Elite.

## Fluoride Dissemination

Fluoride is recognized as an effective means of preventing cavities. However, fluoride effects do not occur uniformly in the mouth, probably because it is not equally delivered to all areas of the dentition. An in vitro study at the Allegheny-Singer Research Institute in Pittsburgh, Pennsylvania, by Stoodley and colleagues tested the hypothesis that fluid

streams produced by the Sonicare FlexCare are capable of passing fluoride through a biofilm-covered membrane.<sup>14</sup> The results not only confirmed their hypothesis, but also showed that the effect achieved by the FlexCare was superior to a rotating-oscillating power toothbrush.<sup>14</sup>

### Sanitizer

The Sonicare Ultraviolet (UV) Sanitizer included with some models of FlexCare (Figure 7) addresses user concerns about the cleanliness of the brush head. A toothbrush can harbor millions of microorganisms, including yeasts, molds, viruses, and bacteria, and the humid bathroom environment may promote the growth of these microorganisms. The Sonicare UV Sanitizer has been demonstrated to effectively reduce the number of viable microorganisms through in vitro laboratory experiments after a 10-minute exposure of UV light directed at the brush head (data on file).

Using the Sonicare UV Sanitizer is simple. Up to 2 brush heads can be placed inside, the door is closed, and the unit is activated to run for 10 minutes. At the conclusion of the sanitization cycle, the unit automatically turns off, leaving sanitized brush heads ready for the next use. A lockout feature prevents operation of the sanitizer if the door is open at any time during the sanitization cycle.

### Conclusion

Philips Oral Healthcare is pleased to introduce the new FlexCare platform of Sonicare power toothbrushes. With collaborations from colleagues around the world, this platform offers superior technology and design, improved performance, and the core cleaning experience that millions of Sonicare users employ daily to optimize their oral health. The in vitro and in vivo substantiation studies that support this innovative platform further the evidence-based core of the science behind Sonicare.

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Chicago, IL) with the preparation of this manuscript is gratefully acknowledged.

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# In Vitro Evaluation of Interproximal Biofilm Removal with Power Toothbrushes

## Abstract

The purpose of this study was to evaluate and compare the efficacy of interproximal plaque removal between 2 power toothbrushes, the Sonicare FlexCare (FlexCare) and the Oral-B Professional Care 9000 Triumph (Triumph). An in vitro tooth model was used to evaluate the brushing efficacy of both active toothbrushes in removing dental plaque biofilm from the interproximal spaces of mandibular molar teeth, which are typically beyond the reach of toothbrush bristles. Microcosmic oral biofilms from pooled saliva were grown in a constant depth film fermenter for 8 days on hydroxyapatite (HA) disks. Disks were then inserted between a pair of molar teeth in the tooth model 2 mm to 4 mm from the bristle tips. Toothbrushing was performed for 15 seconds with no direct contact made between the bristles and the plaque biofilms on the HA disks. Plaque removal efficacy was determined by the percentage of viable bacteria removed from the disks as a result of brushing. The active FlexCare toothbrush removed a significantly higher percentage of biofilm bacteria compared with the inactive state ( $P < .0001$ ) and with the active Triumph toothbrush ( $P = .0001$ ). Moreover, the active FlexCare toothbrush had a slightly greater than 3-fold plaque removal efficacy compared with the active Triumph toothbrush.



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Dental plaque is a multispecies biofilm of microorganisms that grows as an ecosystem on hard and soft tissues in the oral cavity.<sup>1,3</sup> Biofilm formation is most prevalent on the hard tissues, particularly tooth enamel. Regular removal of dental plaque is essential for maintaining oral health. Uncontrolled proliferation of bacteria in the oral biofilm, often as a result of an ecological imbalance, can lead to caries, gingivitis, and even periodontal disease.<sup>2,3</sup>

A variety of oral hygiene products geared toward removal of dental plaque and prevention of further biofilm accumulation have been developed. Such products are intended to supplement regular toothbrushing. Dental plaque is mechanically removed via direct contact and movement of toothbrush bristles across tooth and gum surfaces. Control of toothbrush movement can be manual or through the use of mechanically powered toothbrushes that generate uniform bristle motion. The use of dental floss or proxibrushes to remove dental plaque is also based on their direct contact with plaque on tooth surfaces.<sup>4</sup>

One constant problem encountered in oral hygiene is dealing with plaque removal in hard-to-reach areas of the oral cavity, such as the interproximal regions and posterior teeth. Oral irrigators, which project a high-velocity fluid jet to shear away dental plaque in interproximal surfaces, are not always effective.<sup>4</sup> Power toothbrushes were originally

developed so that specific brush head movements (vibrations, rotations, or oscillations) would remove dental plaque via direct physical contact between the bristles and tooth surface.<sup>1,5</sup> The Sonicare<sup>®</sup> toothbrush integrated direct mechanical brushing with increased bristle velocity, increased brush stroke frequency (at 260 Hz), and novel brush head movements to generate localized hydrodynamic shear forces in the mouth. The combination of direct mechanical brushing and fluid dynamic activity improved targeted plaque removal efficacy, particularly in these hard-to-reach proximal areas. Clinical studies have demonstrated superior performance of the Sonicare toothbrush over a manual toothbrush in removing supragingival plaque in interproximal surfaces.<sup>6,7</sup>

Early studies providing evidence that fluid forces induced by Sonicare toothbrushes removed oral biofilm from dental surfaces were derived from *in vitro* models.<sup>8-10</sup> As methodology developed, the biofilm was placed in the interproximal space of a typodont model to specifically assess dental plaque removal efficacy in areas ordinarily inaccessible by toothbrush bristles.<sup>11</sup> Subsequent *in vitro* studies showed that the fluid forces associated with the Sonicare toothbrushes removed significantly more interproximal biofilm than rotating-oscillating power toothbrushes.<sup>12,14</sup>

The purpose of this study was to evaluate interproximal biofilm removal of the new Sonicare FlexCare power toothbrush with a contemporary rotating-oscillating power toothbrush using a proven *in vitro* biofilm model.<sup>12,15</sup>

### Materials and Methods

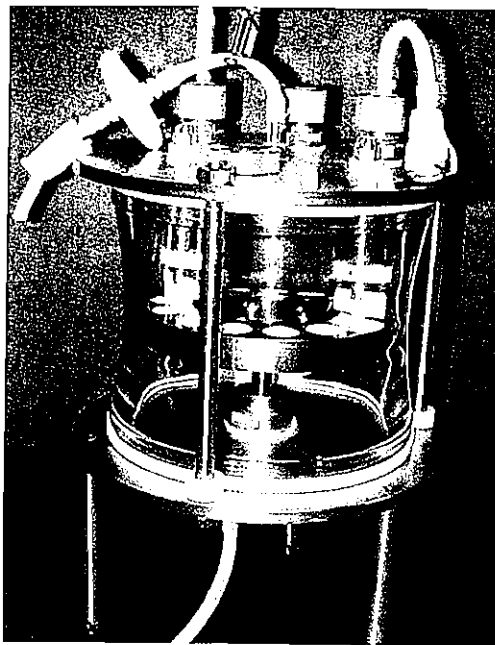
The biofilm removal test closely adhered to the methodology employed by Hope and Wilson.<sup>12</sup> This methodology was developed to evaluate the ability of fluid-induced forces generated by power toothbrushes to remove dental plaque biofilm from interproximal surfaces beyond the reach of the bristle. The model employs a constant depth film fermenter (CDFF) (Figure 1). The CDFF has been shown to produce steady-state oral biofilm communities and plaque structures similar to those occurring on the tooth surface.<sup>16,17</sup> The CDFF biofilm provides a measure of the ability of an oral hygiene device to remove plaque biofilm accumulated in interproximal spaces.

### Treatment Arms

Three treatment arms were used in this test: the new Sonicare FlexCare (FlexCare) power toothbrush with the ProResults standard brush head as

<sup>1</sup>Philips Oral Healthcare, Inc; Snoqualmie, WA.

Figure 1—A model of the CDFF containing HA disks used to grow biofilms for evaluation of FlexCare and Triumph toothbrushes



CDFF = constant depth film fermenter; HA = hydroxyapatite.

the test device; the Oral-B Triumph Professional Care 9000 (Triumph)<sup>®</sup> with the FlossAction brush head as a comparative rotating-oscillating power toothbrush; and an inactive control, the FlexCare toothbrush, switched off so there was no bristle movement. Any biofilm bacteria removed in this control arm represent bacteria spontaneously released from the biofilm surface as a result of non-bristle-induced forces within a fluid environment. The devices were tested without toothpaste, because active components within the toothpaste could alter bacterial viability.

### Specimen Preparation

Saliva samples collected from 30 individuals in good oral health (age range, 18-40 years) were processed and stored at -20°C for use in inoculating the CDFF chambers. The CDFF chambers contained 75 hydroxyapatite (HA) disks, 2 mm in diameter, arranged in 15 pans (5 disks per pan) on which the biofilm was grown at a constant depth of 200 µm. The biofilm was allowed to develop for 8 days of growth under aerobic conditions at 37°C with 5% CO<sub>2</sub>. Upon harvest from the CDFF, biofilms from selected HA disks were used in 1 run of the brushing experiment. Treatment order randomization for the

<sup>®</sup>Procter & Gamble Co; Cincinnati, OH.

biofilm-coated HA disks was performed by a selection matrix that allowed laboratory staff to remain blinded to the nature of treatments and outcomes. A pan containing disks was removed as needed and requisite disks selected with any remaining disks returned to the CDFF to prevent desiccation of the biofilms. Care was taken not to disturb the biofilm when removing the pans or manipulating the disks. Disks were then transferred to the typodont for testing by the brushing apparatus.

#### Brushing Experiments

Fully charged power toothbrushes were positioned with respect to the typodont tooth section according to each manufacturer's instructions. Separation between the bristles and the interproximally located HA disks was visually set at 2 mm to 3 mm as the active toothbrush was moved across the typodont. A pair of biofilm-coated HA disks was placed in interproximal recesses between representative mandibular molars, one on either side of the interproximal space flush with the surface of the tooth. In this location, the biofilm-coated HA disks represented plaque on the interproximal tooth surface. The exposure chamber was filled with 7 mL of phosphate-buffered saline (PBS) solution to mimic fluid levels at the dentition during a typical brushing. Treatment order was randomized.

The load force between the brushes and the teeth conformed to a value derived from conventional use of both powered toothbrushes. After each brushing (15 seconds for the 5-tooth typodont section), the fluid in the brushing chamber containing biofilm bacteria removed as a result of the power toothbrushes was completely extracted with a disposable curved syringe. The fluid was transferred to sterile 15-mL conical tubes. Paired disks containing remnant biofilms were aseptically transferred into 7-mL PBS solution, vortexed for 10 minutes, and probe-sonicated for 10 seconds to eliminate remaining bacteria not removed by fluid forces. Fluid representing bacteria eradicated by the power toothbrushes and that remaining on disks were both diluted 1:10 (1 mL of fluid to 9 mL of sterile PBS solution). Aliquots of this dilution were then plated on tryptic soy agar plates supplemented with 5% sheep's blood. Plates were incubated aerobically at 37°C for 24 hours in 5% CO<sub>2</sub> before bacterial colonies were enumerated.

This study consisted of a single run of the CDFF for a total of 8 paired replicates for each of the 3 treatment arms. Colony-forming units (CFUs) were recorded for each of the replicates and normalized to the volume of brushing fluid sampled (CFU/mL) to represent

the amount of biofilm removed with that test.

#### Statistical Analysis

Triplicate viable count data were used to calculate mean CFU/mL for each replicate. The percentage of biofilm removal from the disk relative to total counts (sum of bacteria removed from disks as a result of treatment and bacteria remaining on disks) was determined. In the subsequent analysis of variance, percentage reduction was the dependent variable and the treatment group was the independent variable, with  $P = .05$  defined as the level of significance. FlexCare was the active control compared with Triumph active and FlexCare inactive, using Dunnett's multiple comparison test.

#### Results

As expected, baseline pretreatment data showed no significant differences among treatment average counts ( $P > .94$ ), so that all 3 treatments exhibited comparable initial conditions, about 10<sup>7</sup> CFU/mL for all samples.

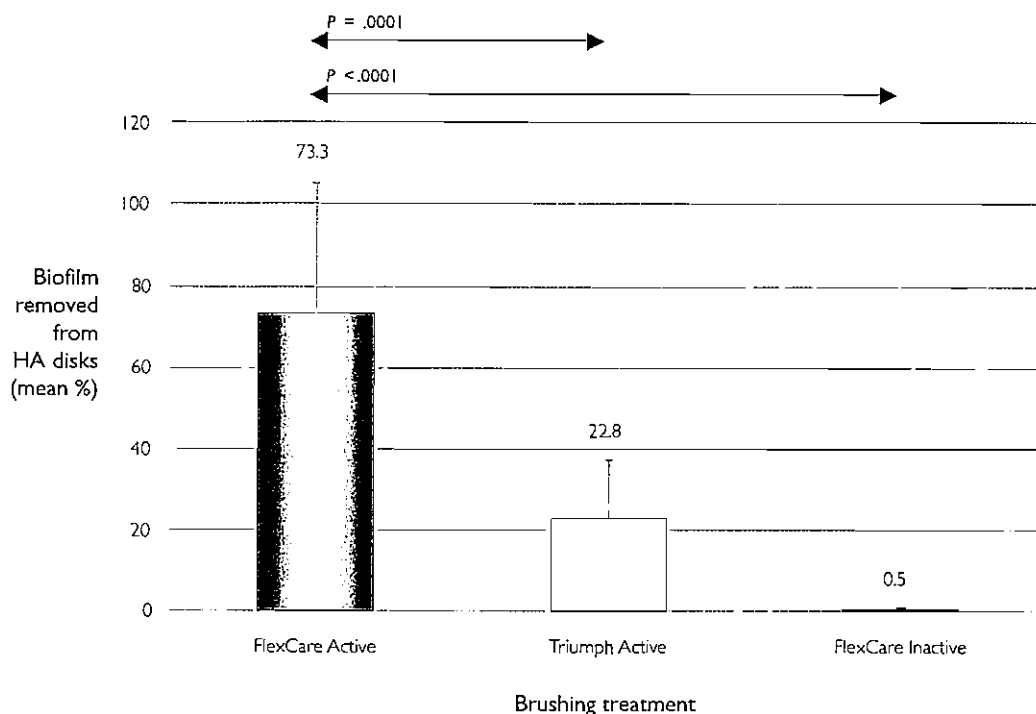
Figure 2 shows that the percentage of plaque biofilm from interproximal spaces in the typodont model was 73.3% for the active FlexCare, 22.8% for the active Triumph, and 0.5% for the inactive FlexCare. The percentage of interproximal plaque biofilm removal by the active FlexCare was significantly higher than both the inactive brush ( $P < .0001$ ) and the active Triumph ( $P = .0001$ ). Based on the percentage of biofilm bacteria removed, the efficacy of biofilm plaque removal by the active Sonicare FlexCare toothbrush was 3.2 times greater than the active Oral-B Triumph toothbrush.

#### Discussion

Dental plaque biofilm develops on hard surfaces, such as teeth in the oral cavity. Conventional toothbrushes that clean tooth surfaces remove dental plaque primarily in areas that are directly accessible to the bristles. However, accumulation of dental plaque also occurs in regions inaccessible to the mechanical effects of direct bristle contact. These areas include interproximal spaces, the sulcus, the gumline, and tooth pits and fissures.

In contrast to conventional toothbrush cleaning, the Sonicare toothbrush has been shown to remove biofilm bacteria beyond the reach of the bristles. Fluid forces generated by the rapid motion of the Sonicare brush head bristles are channeled into interproximal regions that the bristles cannot contact directly. The dynamic fluid motion removes plaque biofilm in these hard-to-reach areas.<sup>9,11-13</sup>

Figure 2—Mean percentage biofilm (in CFU/mL) removed from HA disks by active treatment with FlexCare and Triumph



CFU = colony-forming unit; HA = hydroxyapatite.

Data from these experiments are consistent with earlier findings, which revealed that fluid activity associated with the Sonicare toothbrush removed more biofilm in the interproximal space than a power toothbrush with rotating-oscillating motion.<sup>12,13,18</sup> Results from the present study demonstrate a 3-fold greater removal of interproximal biofilm bacteria with the new Sonicare FlexCare power toothbrush than with the Oral-B Triumph toothbrush. Interestingly, this 3-fold reduction pattern of interproximal plaque biofilm was also observed in previous studies comparing earlier Sonicare models (Sonicare Plus and Sonicare Elite) with Oral-B models.<sup>12,13</sup> This superior performance is probably due to the magnitude and the direction of the fluid motion generated by the Sonicare toothbrush. Fluid is actively propelled into interproximal areas between the teeth, rather than along the same side of the dentition as the bristles (such as the smooth facial or lingual surfaces of the teeth), as appears to occur with rotating-oscillating toothbrushes. In addition, the FlexCare toothbrush likely demonstrated a heightened velocity of fluid flow through the interproximal spaces, thereby increasing biofilm dislodgement in these hard-to-reach areas.

Another observation made was the increased generation of bubble activity by the Sonicare FlexCare toothbrush when compared with the Triumph toothbrush. Bubbles have a propensity to create localized fluid forces that act to displace biofilms from a substratum.<sup>19-21</sup> It is possible that the heightened bubble activity generated by the bristle movements of the Sonicare FlexCare toothbrush was more effective in channeling these localized fluid forces into the concealed niches of interproximal areas.

### Conclusion

In summary, when comparing 2 active powered toothbrushes, hydrodynamic fluid forces generated by the Sonicare FlexCare induced a 3-fold greater reduction of interproximal plaque biofilm than Oral-B Triumph. The results of this in vitro study have demonstrated that the Sonicare FlexCare toothbrush removes a significantly higher percentage of plaque biofilm in interproximal areas than the Oral-B Triumph toothbrush.

### Acknowledgment

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# Effect of the Sonicare FlexCare Power Toothbrush on Fluoride Delivery Through *Streptococcus mutans* Biofilms

## Abstract

Caries are caused by dental plaque biofilms that create acids when they metabolize dietary sugars such as sucrose. Fluoride can prevent caries by (1) enhancing remineralization of tooth enamel, (2) reducing enamel solubility in acidic conditions, and (3) inhibiting or modifying biofilm metabolism and reducing acidification. The efficacy of fluoride is not systemic but topical. Therefore, more effective delivery of fluoride to stagnation sites, such as the interproximal regions of posterior teeth, may contribute to the reduction of caries in these regions. Power brushing generates turbulence and currents in the fluid (ie, toothpaste-saliva mixture), and it is expected to increase the delivery of fluoride and other solutes into otherwise stagnant areas. To test this hypothesis, we used a 2-chamber method in which we measured the rate at which fluoride passed from one chamber into the other through a biofilm-colonized cellulose ester membrane under 3 conditions: no brushing, rotary power brushing (Oral-B Triumph Professional Care 9000), and sonic brushing (Sonicare FlexCare). For comparative purposes, we used the mass transfer coefficient (K) of fluoride, which is a measure of how quickly fluoride is delivered through the biofilm-colonized membrane. Power brushing significantly increased the delivery rate of fluoride through the biofilm compared with no brushing ( $P < .001$ ). Rotary brushing increased the mass transfer coefficient of fluoride through the biofilm-colonized membrane by 79% ( $P = .002$ ), whereas sonic brushing generated the greatest increase of 129% ( $P < .001$ ). Sonic brushing generated a fluoride mass transfer coefficient that was 29% greater than that of rotary brushing ( $P < .05$ ). This *in vitro* study supports an earlier clinical study that reported sonic brushing generated the greatest concentration of fluoride in interproximal plaque, followed by rotary brushing and manual brushing.



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The accumulation of dental plaque biofilms is responsible for caries,<sup>1</sup> gingivitis, and periodontitis.<sup>2</sup> Acidogenic streptococci, including *Streptococcus mutans*, are early colonizers of cleaned tooth surfaces and are causative agents of caries.<sup>3</sup> *S mutans* produces lactic acid from the fermentation of sucrose, which can reduce the pH to below 5, increasing dissolution of hydroxyapatite, which makes up more than 95% of tooth enamel. Fluoride has long been an effective preventive measure against dental caries, as an additive to drinking water and by the daily use of fluoridated dentifrices and rinses. Despite long-standing evidence of fluoride's anti-caries effect, its mechanism of action remains under investigation. Three main mechanisms have been proposed to explain the success of fluoride in combating caries: (1) reduced enamel solubility, (2) inhibition of bacterial acid production, and (3) effect in demineralization/remineralization reactions.<sup>4-7</sup> In reduced enamel solubility, for example, fluoride ions can replace hydroxyl ions in hydroxyapatite, forming fluorapatite, and thereby reducing the susceptibility

to acidic attack by lowering the onset of acidic dissolution from pH 5.5 to approximately pH 4.5.<sup>5,7</sup>

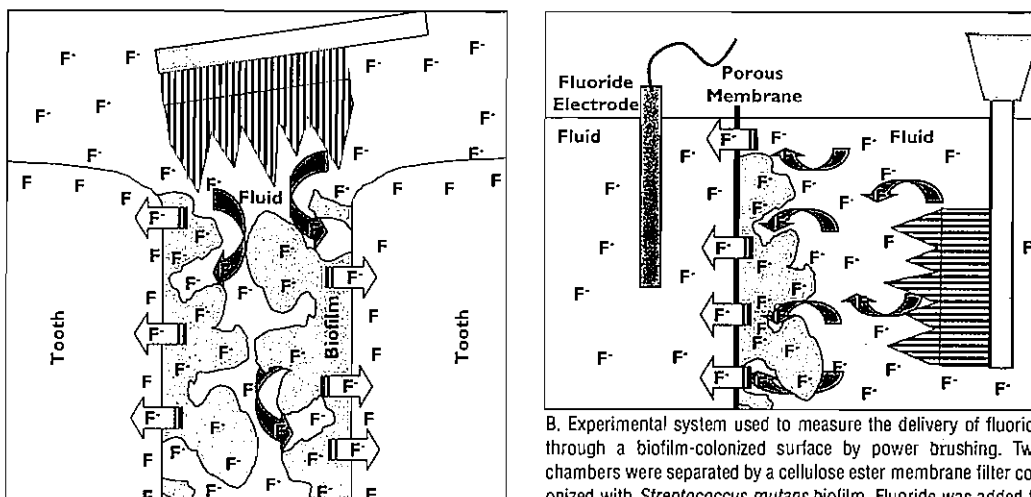
Fluoride also has been shown to reduce bacterial acidogenicity by modulating microbial physiology<sup>4,7,12</sup> or even acting as an antimicrobial agent.<sup>13</sup> However, as noted by van Loveren,<sup>13</sup> most of the work supporting this theory has been developed in vitro, and it is not certain whether the antimicrobial action of fluoride is at work in vivo or to what extent it contributes to the prevention of caries. The more prevalent explanation concerns fluoride's role in the remineralization-demineralization cycle that the tooth enamel is continuously undergoing.<sup>3</sup> Fluoride inhibits the demineralization process and enhances the remineralization process.

Interestingly, biofilm plaque also may have a positive interaction with fluoride. Fluoride, which enters the plaque during exposure to fluoridated drinking water or dentifrice, may bind to biofilm cells or slime matrix components.<sup>14,15</sup> Once the fluoride source is gone, bound fluoride in the plaque may be slowly released over time, prolonging the anticaries activity. In this case, the biofilm actually acts as a fluoride storage reservoir. Although, ideally, power brushing is designed to remove as much

plaque as possible, in the instances where complete plaque removal cannot be achieved (eg, interproximal regions of posterior teeth), then the increased delivery of fluoride into the biofilm by hydrodynamic forces may enhance the period of fluoride efficacy by the reservoir effect.

Regardless of the relative contribution of the 3 proposed modes of action to fluoride efficacy, it is the topical, rather than systemic delivery of fluoride that results in caries protection. Therefore, it is not only the concentration of fluoride in the salivary fluid that is important, or the frequency of fluoride exposure, but also how effectively fluoride is delivered to the sites in which caries are problematic and persistent. Daily brushing with fluoride toothpaste daily can effectively prevent caries in easily accessible areas. However, dental plaque biofilms formed in stagnant areas within the dentition may still lead to caries. For this reason, good oral hygiene and the delivery of fluoride into tooth regions with limited access are important. The motion from a sonic toothbrush has been shown in vitro to provide fluid dynamic action<sup>16,17</sup> by virtue of driving fluid beyond the reach of the bristles to remove biofilm from flat surfaces as well as interproximal spaces.<sup>18</sup> It is, there-

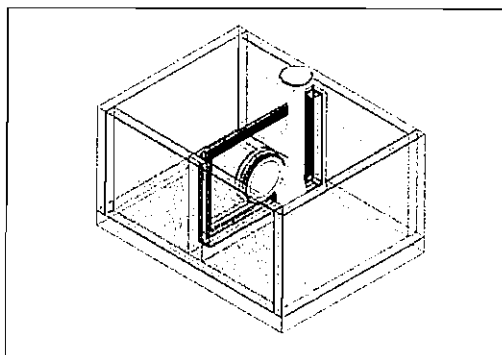
Figure 1—Schematic showing the interactions between fluoride in the fluid (saliva, mouthwash, or dentifrice), the plaque biofilm, and the teeth



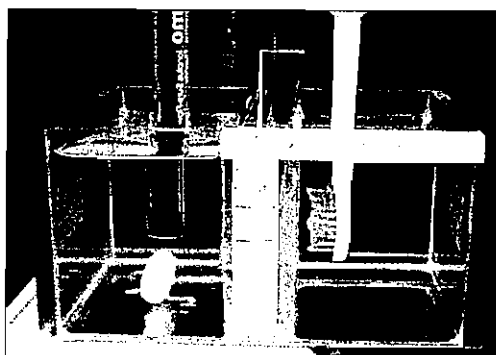
A. Interproximal aspect. Hydrodynamic forces caused by power brushing drives fluid (blue arrows) containing fluoride ion ( $F^-$ ) into the interproximal space and through biofilm channels to the tooth surface. Some fluoride is absorbed into the tooth hydroxyapatite (gray arrows), reducing enamel dissolution during acidic production. Some fluoride enters the biofilm (green), which can act as a reservoir, releasing fluoride to the tooth even after a fluoride-containing dentifrice is removed. Fluoride in the biofilm may also kill or inactivate plaque bacteria so that the pH does not drop as much on exposure to sugar.

B. Experimental system used to measure the delivery of fluoride through a biofilm-colonized surface by power brushing. Two chambers were separated by a cellulose ester membrane filter colonized with *Streptococcus mutans* biofilm. Fluoride was added to the right side of the chamber and the brush activated. A fluoride-specific electrode in the left chamber was used to measure the fluoride concentration buildup over time.

Figure 2—Experimental system used to measure the rate of fluoride delivery through the *Streptococcus mutans* biofilm-colonized membrane



A. Schematic showing the orientation of the brush to the biofilm-colonized membrane (yellow). The right biofilm chamber and left measurement chamber were separated by a water-tight partition containing a support holding the biofilm-colonized membrane.



B. Actual unit showing a sonic brush in the biofilm-side chamber with the fluoride electrode in the measurement-side chamber.

fore, reasonable to consider that fluid dynamics can also aid in the penetration of fluoride deeper into, or even through, a plaque biofilm, thereby providing the extra few parts per million (ppm) of fluoride that has been suggested to be beneficial for the added protection against caries.<sup>5</sup> The US Public Health Service has established the optimal level for fluoride content in drinking water to be in the range of 0.7 ppm to 1.2 ppm.<sup>10</sup> Figure 1A shows various possibilities for the distribution of fluoride in the oral fluid, the biofilm, and the tooth enamel from an interproximal aspect.

Clearly, it is important to understand how fluoride is transported through dental biofilms; however, very little is known concerning this process. A seminal study by Watson and colleagues<sup>20</sup> subsectioned plaque to determine a spatially averaged fluoride profile and concluded that fluoride penetration was restricted within the biofilm. However, because fluoride was only measured in the biofilm, not in channels and voids and not at the substratum, it was not clear how a heterogeneous biofilm-colonized surface may influence transportation to the underlying surface. A clinical study by Sjögren and colleagues<sup>21</sup> found that sonic brushing for 4 days significantly reduced the amount of interproximal plaque compared with a rotary or manual brush. Interestingly, sonic brushing also increased the fluoride concentration in the plaque by 40% compared with the other treatments, suggesting that sonic brushing increased the delivery of fluoride through biofilms.

To investigate the extent to which power brushing may increase the delivery of fluoride through biofilms, we utilized a 2-chamber method<sup>22-24</sup> by

which 2 chambers are separated by a permeable membrane colonized with biofilm. Sodium fluoride, the solute of interest in this study, is added to one chamber. The other chamber is continuously monitored for the appearance of the solute, and the increase in concentration over time can be used to determine how quickly the solute was able to pass through the biofilm-colonized membrane. *S. mutans* biofilms grown on cellulose ester membrane filters were used as the model dental plaque. The transport of fluoride with no brushing (diffusion alone) was compared with power brushing by sonic and rotary brush mechanisms. Figure 1B shows the arrangement used to determine the extent to which power brushing increased the delivery of fluoride through a biofilm-colonized membrane.

## Materials and Methods

### Structure of Real and Laboratory-grown Dental Biofilms

To illustrate the key features of real dental biofilms, standardized coupons of human enamel were worn by one of the investigators in the region of the premolars and molars for 3 days. The coupons were removed and stained for bacteria in general (red) or streptococci (yellow) specifically, as detailed in the study by Hall-Stoodley and colleagues (Figure 3).<sup>25</sup> The slime matrix produced by the bacteria was stained blue. A Leica TCS SP2 confocal system<sup>2</sup> was used, which allowed 3-dimensional imaging. Biofilms were also grown from the model plaque organism, *S. mutans* UA159 (ATCC# 700610) on brain heart infusion (BHI) broth supplemented with

<sup>2</sup>Leica Microsystems, Wetzlar, Germany.

2% sucrose in MatTek culture plates<sup>b</sup> at 37°C and 5% CO<sub>2</sub>. The culture medium was replaced daily with fresh 37°C medium over a 3-day culture period. The biofilms were stained to show the bacterial cells in green and the slime matrix in blue. The images were constructed using Imaris software.<sup>c</sup>

#### Diffusion Chamber

A previously developed method<sup>22,24</sup> was used to assess the effect of power brushing on the diffusion of fluoride through biofilms. A specially designed 2-chamber diffusion chamber was fabricated from polycarbonate (Figure 2).

The 2 chambers were separated by a cellulose ester membrane. By growing biofilms on the membrane and measuring how quickly fluoride passed from one chamber to the other, we could measure the effect of power brushing on delivering fluoride through the biofilm-colonized membrane. The membrane filter holder was easily inserted into the diffusion chamber allowing rapid replacement with new biofilm-colonized filters for repeated measurements. First, the biofilm-side chamber (right-hand chamber) was gently filled with 1100 ppm sodium fluo-

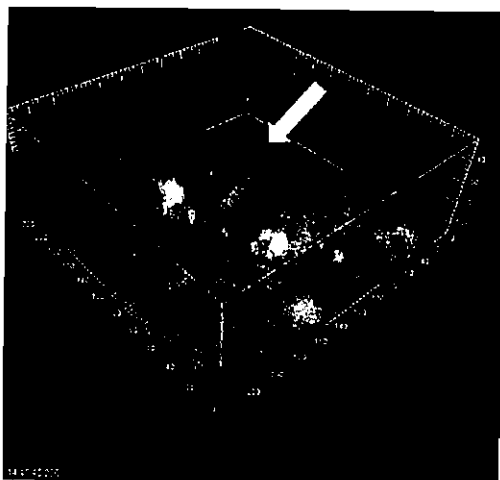
ride solution in phosphate buffer salts (PBS). The measurement-side chamber contained PBS with approximately 0.5 ppm fluoride. By starting with a small concentration of fluoride in the measurement chamber, the stabilization time of the electrode was decreased. Thus, at time zero, the measurement-side chamber had 0.5 ppm fluoride, whereas the biofilm-side chamber had 1100 ppm. The filling process took approximately 5 seconds. The appearance of fluoride in the measurement chamber, after traveling through the biofilm and the membrane, was measured by an ion-selective fluoride electrode. The measurement-side chamber was mixed vigorously with a magnetic stir bar. Over the 4-minute monitoring period, the concentration in the biofilm-side chamber never fell to less than 1050 ppm, so it was assumed that the concentration gradient driving the fluoride flux was constant.

#### Biofilm Growth for Diffusion Measurements

Biofilms were grown on the cellulose ester membranes from *S. mutans* UA159 by immersing a filter holder, with an attached filter, in each well of a 6-well plate with 5 mL of BHI and 2% sucrose. Because the filter assemblies were slightly buoyant, they floated, so that the filter surface was level with

<sup>b</sup>MatTek Corp; Ashland, MA.  
<sup>c</sup>Bitplane, AG; Zurich, Switzerland.

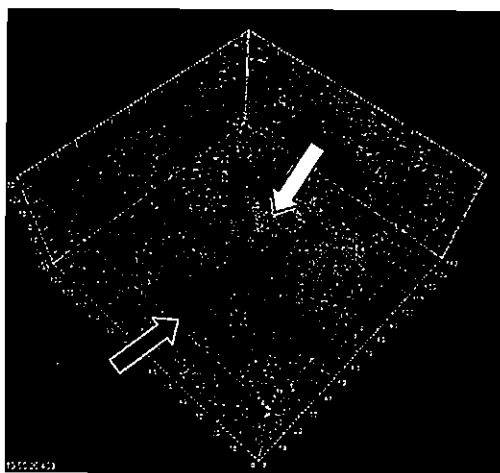
**Figure 3**—The dental plaque bacterial biofilms were composed of dense clusters of bacteria attached to the surface, enveloped in a protective extracellular polymeric slime (EPS) matrix



**A.** Three-dimensional (3-D) confocal image of a natural dental biofilm grown in vivo on an enamel surface positioned in the region of the premolars and molars for 3 days. Fluorescent in situ hybridization was used to identify specific bacteria. All bacteria were stained red with a universal probe. Streptococci were stained yellow. The enveloping slime matrix is shown as blue. The EPS in the foreground was made transparent using the Imaris 3-D rendering software (Bitplane) allowing the bacteria inside to be visible. In some places, channels (white arrow) protruded all the way through the biofilm to the enamel underneath. Scale: major grid divisions are 20 µm.



**B.** 3-D confocal image of a laboratory-grown *Streptococcus mutans* biofilm showing individual cocci (green) enveloped in a slime matrix (blue). Scale: major grid divisions are 10 µm.



**Figure 4**—Three-dimensional view of *Streptococcus mutans* biofilm grown on the cellulose ester membrane. The bacterial cells were stained green with nucleic acid stains. Like real dental biofilms, the biofilm was patchy and consisted of dense clusters of cells (white arrow) separated by channels (black arrow). Some of the channels penetrated down to the membrane surface. Scale: major grid divisions are 10  $\mu$ m.

the medium level and constantly wetted. Thus, the filter was continuously coated with a thin liquid film, with the overlying 5% CO<sub>2</sub> headspace making it comparable with growth conditions for our previous dental biofilm studies.<sup>16,18</sup> Each well was inoculated with 1 mL midlog phase *S. mutans* shake flask culture. The 6-well plate was positioned on a shaking table in a 5% CO<sub>2</sub> 37°C incubator. The biofilms were grown for 3 or 4 days. The medium was replaced daily with fresh sterile medium. After the growth period, the biofilm-colonized membranes were quickly transferred to the diffusion chamber half-cell for the diffusion measurements.

#### Fluoride Measurement

An Orion 9609BN Ionplus Sure-Flow combination electrode<sup>d</sup> with reference electrode connected to a standard pH/mV meter<sup>e</sup> was used to measure fluoride coming through the biofilm-colonized membrane. Data were recorded using a data acquisition I/O device.<sup>f</sup> The electrode was calibrated daily. Once the biofilm-colonized membrane was in place, measurements were taken over a 4-minute period. Fourteen replicate measurements were performed with no brushing and 17 replicates were performed with each of 2 power brushes.

<sup>d</sup>Thermo Electron Corp; Waltham, MA.

<sup>e</sup>Radioner Analytical, model PHM210; Lyon, France.

<sup>f</sup>National Instrument DAQCard-LA-16XE-50, 16 bit; Austin, TX.

#### Power Brushes

Two power brushes were compared with an unbrushed condition: the Sonicare FlexCare<sup>g</sup>, with ProResults standard brush head, and the rotary motion Oral-B Triumph Professional Care 9000<sup>h</sup> (Triumph), equipped with the FlossAction brush head. The brush heads were placed 1 cm from the biofilm-colonized filter to minimize biofilm removal during the measurement, because we were interested in the delivery of fluoride through a biofilm-colonized membrane. Some of the membranes were stained before and after exposure to power brushing to assess the effect of brushing on biofilm removal. Biofilm thickness, surface area coverage, and biomass were measured using the COMSTAT<sup>i</sup> image analysis software.<sup>3a</sup> At a distance of 10 mm, power brushing reduced the amount of biofilm by 36% over the 4-minute period; however, this difference was not significant from the unbrushed situation ( $P = .63$ ; number of samples = 19). As expected, there was also no significant difference in biofilm removal between the FlexCare and Triumph ( $P = .23$ ;  $N = 12$ ).

#### Estimation of Rate of Fluoride Delivery Through a Biofilm-colonized Membrane

To compare the effect of power brushing on the rate of fluoride delivery through the biofilm-colonized membrane, the mass transfer coefficient from the fluoride concentration time data was calculated. The mathematics used were discussed in literature by Bryers and Drummond.<sup>2a</sup> The mass transfer coefficient is a measure of the speed at which fluoride flows through the biofilm and membrane from the biofilm-side chamber to the measurement-side chamber.

#### Statistics

Data sets were statistically compared using 1-way analysis of variance.<sup>j</sup> Differences were considered significant at  $P < .05$ .

#### Results

##### Structure of Real and Laboratory-grown Dental Plaque Biofilms

After 3 days, the biofilms consisted of aggregates of bacteria enveloped in a slime matrix (Figure 3). In the real dental plaque biofilm, there were water channels that, in some cases, penetrated down to the enamel surface. Streptococci were present throughout the biofilm mixed with other bacteria, some-

<sup>g</sup>Philips Oral Healthcare, Inc; Snoqualmie, WA.

<sup>h</sup>Procter & Gamble Co; Cincinnati, OH.

<sup>i</sup>Center for Biomedical Microbiology; Lyngby, Denmark.

<sup>j</sup>Microsoft Excel 2000; Redmond, WA.

times as single cells and sometimes as larger colonies. The biofilm was approximately 50  $\mu\text{m}$  thick. The laboratory-grown *S. mutans* demonstrated similar characteristics of aggregated bacteria: interspersed with water channels and enveloped in a slime matrix.

#### *Biofilm Growth on Cellulose Ester Membranes*

*S. mutans* biofilms grew readily on the cellulose ester membranes. The biofilms were similar to those described above and in the literature<sup>15,16</sup> and consisted of dense aggregates of cell clusters interspersed with water channels that penetrated to the membrane filter surface (Figure 4).

The biofilms ranged in maximum thickness from 20  $\mu\text{m}$  to 80  $\mu\text{m}$  with an average of 45  $\mu\text{m} \pm 25$   $\mu\text{m}$  (mean  $\pm$  1 SD) and had a surface coverage of between 50% and 75%.

#### *Delivery of Fluoride Through Biofilm-colonized Membranes With and Without Power Brushing*

When the 1100-ppm fluoride solution was added to the biofilm side of the diffusion chamber, an increase in fluoride concentration was measured in the other chamber after approximately 1 minute, even without power brushing. The increase was due to Fickian diffusion caused by the difference in fluoride concentration between the 2 chambers (Figure 5). After 4 minutes, the concentration had increased from approximately 0.4 ppm to 0.5 ppm. Power

brushing greatly increased the delivery of fluoride through the biofilm membrane, with FlexCare causing the greatest increase over the 4-minute brushing period. The fluoride concentration in the measurement side with power brushing from FlexCare achieved approximately 0.8 ppm, whereas that from Triumph achieved approximately 0.65 ppm. Without brushing the mass transfer rate coefficient of fluoride through the biofilm-colonized membrane was  $1.6 \pm 0.3 \times 10^{-5}$  cm/s (Figure 6). This was increased by 79% to  $2.8 \pm 0.2 \times 10^{-5}$  cm/s by power brushing with Triumph and by more than twice as much (129%) to  $3.6 \pm 0.3 \times 10^{-5}$  cm/s by FlexCare (Table). The mass transfer rate for FlexCare was also 29% more than for Triumph.

#### *Discussion*

This article describes a 2-chamber method to quantify and compare the delivery (mass transfer) of fluoride through biofilm-colonized membranes under various conditions of power brushing and nonbrushed diffusion. These systems have been previously applied to study the transport of medically relevant molecules<sup>22</sup> and tracer salts or nutrients<sup>23,24</sup>; however, they have not been used to study the transport of fluoride through biofilm-colonized membranes in a dental context. Two-chamber systems have the advantage that they do not require microscopic measurement techniques, such as microelectrodes, microfluorescent dye tracking,<sup>27</sup> or fluorescent recovery after photobleaching,<sup>22</sup> but have the

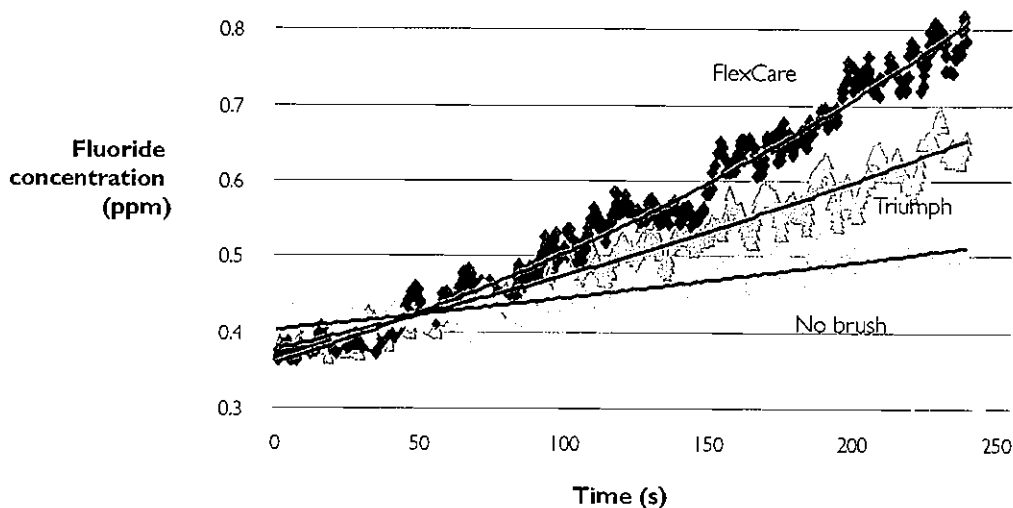


Figure 5—Representative data set showing the rate of fluoride delivery through the biofilm-colonized membrane measured over a 4-minute period with no brushing (yellow diamonds) or power brushing with either FlexCare (blue diamonds) or Triumph (gray triangles). Power brushing increased the fluoride delivery, with FlexCare causing the greatest increase in fluoride concentration after the 4-minute period.

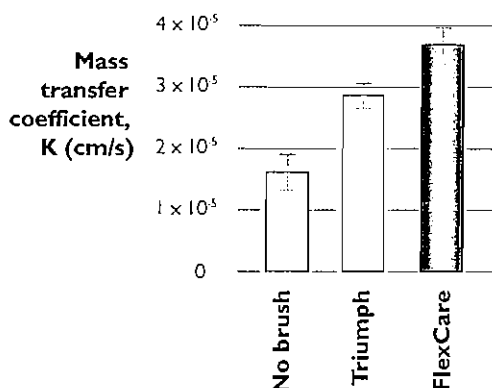


Figure 6—The mass transfer coefficient (a measure of the rate of delivery of fluoride through the biofilm-colonized membrane) generated by power brushing was significantly greater ( $P < .05$ ) than that from diffusion alone (no brushing). FlexCare caused an increase of 129% and Triumph caused an increase of 79% over no brushing. The mass transfer coefficient generated by FlexCare was significantly greater ( $P < .05$ ) than that generated by Triumph by 29%. Data are mean  $\pm$  1 standard error.

disadvantage in that biofilm heterogeneity may lead to an underestimation of the transport resistance of biofilms. Channels throughout the biofilm may act as short circuits by which molecules can travel through the biofilm rapidly, whereas those that penetrate into the matrix of the biofilm may travel much slower. However, in this study, the relevant parameter was how fluoride might be more effectively transported through the biofilm to the surface of the tooth by power brushing, regardless of route. Because fluoride microelectrodes are not commercially available, and fluoride is not fluorescent, the 2-chamber method offered the only established method for real-time biofilm transport monitoring.

*S. mutans* biofilms grew readily on the cellulose ester membrane filters and were similar in structure to naturally grown human dental plaque biofilms in the present study and those of Wood and colleagues<sup>28</sup> or *S. mutans* biofilms grown on hydroxyapatite slides in a drip flow reactor.<sup>16,18</sup> The biofilms consisted of cell clusters enveloped in extracellular polymeric slime interspersed with water channels. In some

instances, the water channels penetrated through the biofilm down to the underlying substratum. Power brushing significantly increased the mass transfer coefficient ( $K$ ) of fluoride (essentially the rate of fluoride delivery) through the biofilm-colonized membrane by increasing  $K$  from  $1.6 \times 10^{-5}$  to  $2.8 \times 10^{-5}$  for Triumph and  $3.6 \times 10^{-5}$  cm/s for FlexCare compared with no-brush diffusion only.

There are 2 modes of transport by which solutes can travel through biofilms, diffusion and convection.<sup>27,29</sup> Diffusion occurs in stagnant conditions and is very slow over long distances (ie, 0.1 mm or more). Convection occurs when there is fluid flow and the transport rate is much faster than diffusion. In the absence of brushing, the system was essentially stagnant, with the exception of slight currents due to small vibrations or temperature gradients in the room, and the flow of fluoride through the biofilm was driven by the concentration difference (diffusion boundary layer [DBL]) of fluoride between the 2 chambers and the naturally developed concentration gradient on the biofilm side of the membrane. However, in the case of power brushing, local turbulence of the brush action creates fluid flow through the biofilm channels, which delivers more fluoride into the biofilm as well as to the filter, increasing the concentration gradient driving fluoride across the membrane more rapidly.

The delivery of fluoride (flux) is directly proportional to the concentration gradient. As the diffusion boundary layer is reduced by the convection caused by power brushing, the gradient increases and so does the measured flux. The magnitude of decrease in DBL is directly related to the turbulence created in the vicinity of the surface and, therefore, is reflective of the power of the hydrodynamic mixing created by the brushing. Therefore, assuming the amount of biofilm stays the same during a test, any increase in the mass transfer coefficient of fluoride caused by power brushing can be attributed to the generation of greater hydrodynamic forces.

FlexCare generated the greatest fluoride mass transfer coefficient, which was 29% greater than that of Triumph and 129% greater than the no-brush con-

Table—Comparison between the diffusion rate constant ( $K$ ) of fluoride caused by power brushes compared with no brushing through the *Streptococcus mutans* colonized membrane filter (mean  $\pm$  1 standard error). A comparison of Triumph and Sonicare FlexCare is also shown.

Parameter 1	K (cm/s)	Parameter 2	K (cm/s)	Increase (%)	P
No brushing	$1.6 \pm 0.3 \times 10^{-5}$	FlexCare	$3.6 \pm 0.3 \times 10^{-5}$	129	<.001*
No brushing	$1.6 \pm 0.3 \times 10^{-5}$	Triumph	$2.8 \pm 0.2 \times 10^{-5}$	79	.002*
Triumph	$2.8 \pm 0.2 \times 10^{-5}$	FlexCare	$3.6 \pm 0.3 \times 10^{-5}$	29	.03*

\*Statistically significant differences ( $P < .05$ ).

dition. These data indicate sonic brushing created greater hydrodynamic mixing than rotary brushing and are consistent with our previous data showing sonic brushing removed more biofilm than rotary brushing<sup>16,18</sup> and Sjögren and colleagues' clinical study<sup>21</sup> that found sonic brushing generated the greatest concentration of fluoride in interproximal plaque, followed by rotary brushing and manual brushing.

Although the ultimate goal of power brushing is to remove plaque biofilm from all areas of the mouth, including those locations beyond the reach of the bristles, in the challenging areas between teeth in which all biofilm is not removed by hydrodynamic shear forces alone, the increased delivery of fluoride may still provide protection against caries development.

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# A Randomized, Crossover Study to Compare Plaque Removal Ability of Sonicare FlexCare and Elite 9000

## Abstract

The plaque removal efficacy of a new sonic toothbrush, the Sonicare FlexCare, was compared with its predecessor model, the Sonicare Elite 9000, in a single-use, examiner-blind, crossover clinical trial. Eighty-nine subjects were randomized to 1 of 2 treatment sequences. The Turesky Modified Quigley-Hein (TMQH) plaque index was used for efficacy measurements. A TMQH score  $\geq 1.8$  at screening (Visit 1) after 24 hours of oral hygiene abstinence was required for inclusion. At the first of 3 visits, subjects received their assigned toothbrush and toothpaste. They were instructed to use the materials twice daily for 2 minutes during a 6-day familiarization period. Subjects abstained from oral hygiene for 24 hours before returning to the clinic for Visit 2. TMQH scores were appraised before and after a 2-minute supervised brushing episode. Familiarization and plaque accumulation periods and examinations were repeated at Visit 3. Percent change in overall plaque score (before vs after brushing) was the primary efficacy measure. Data were analyzed using a linear mixed effects model. Comparisons between treatment groups were performed using the appropriate F test. A safety analysis was based on all reported adverse events and on oral examinations at all study visits. The study was completed by 87 subjects (61 women, 26 men; mean age, 38.2 years; range, 19-64 years). The sample mean  $\pm$  standard deviation TMQH score at Visit 1 was  $3.10 \pm 0.53$ . Overall scores before brushing were  $2.93 \pm 0.62$  and  $3.03 \pm 0.59$  for Sonicare FlexCare and Sonicare Elite 9000 groups, respectively. Brushing reduced the scores by  $40.6\% \pm 14.5\%$  and  $37.4\% \pm 14.0\%$  for Sonicare FlexCare and Sonicare Elite 9000, respectively. The 2 means were different at  $P = .0039$ . Similar reductions were observed for the subregions, including anterior, posterior, interproximal, and interproximal posterior sites.



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Dental plaque biofilm has long been identified as a critical factor in the etiology of caries, gingival inflammation, and chronic periodontitis.<sup>1,2</sup> Similarly, a link between plaque-induced oral diseases and systemic diseases has been suspected for centuries.<sup>4</sup> It received further support in 1989 when Mattila and colleagues<sup>5</sup> described an association between dental health and acute myocardial infarction. Since then, an increasing number of studies have indicated that certain plaque biofilm bacteria are opportunistic pathogens that could significantly increase the risk for systemic disease.<sup>6-11</sup> Therefore, managing the amount and composition of dental plaque biofilm is relevant for both oral and overall health. There is strong evidence<sup>12</sup> that this can be accomplished through daily oral hygiene routines, including brushing with a fluoride-containing toothpaste and dental flossing.<sup>12</sup>

Although both manual and powered toothbrushes are used in plaque control, there is increasing evidence that power toothbrushes are more effective than manual ones in removing supragingival plaque.<sup>13</sup> Powered brushes use a motor to generate bristle motion and require less manual dexterity. In addition, high-end power toothbrushes have timers

that help users brush for appropriate periods throughout the dentition.

Currently, there are 2 major categories of brush head motion among the most popular power toothbrushes: rotation-oscillation and high-frequency/high-amplitude sweep or sonic. The first sonic power toothbrush, Sonicare Advance<sup>14,15</sup> was introduced in 1992. It was succeeded in 2002 by the Sonicare Elite.<sup>16</sup> Both models generate fluid motion that is strong enough to disturb and remove *in vitro* biofilm in the absence of direct physical contact between bristles and biofilm.<sup>17</sup> Initial-generation sonic toothbrushes, such as the Advance and Elite, exhibited a brush head with a magnetic head-handle interface (HHI) that included the resonator component of the drivetrain.

The Sonicare FlexCare power toothbrush described in this article includes several new features, including a new drivetrain and a simple mechanical snap-on/snap-off HHI. All components of the new drivetrain are now located inside the handle. Finally, the brush head itself was redesigned to incorporate a radial trim; that is, a radial curvature, with the outer tuft columns projecting at a 5-degree angle in relation to the inner tuft columns, allowing for a wider sweep per stroke. No clinical data on this new toothbrush have been published. Therefore, the purpose of this clinical trial was to compare the efficacy of the Sonicare FlexCare with that of its prede-

cessor model, the Sonicare Elite 9000. This article focuses on plaque reduction as assessed in a single-use toothbrushing model.

## Materials and Methods

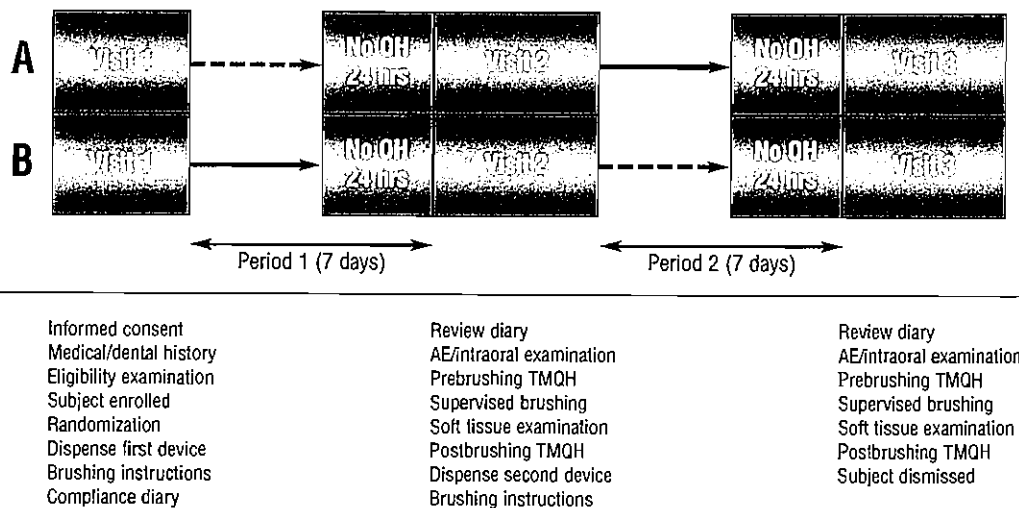
### General Study Information and Design

The single-blind, randomized, crossover study with 2 test groups was executed at the University Park Research Center, Fort Wayne, Indiana. The study included two 7-day brushing periods and 3 visits (Figure 1). Each participant signed a written informed consent form after an explanation of the study protocol. The study was conducted in agreement with the Good Clinical Practice Guidelines of the International Conference on Harmonization<sup>18</sup> and approved by an institutional review board.

**Subjects.** Inclusion criteria were a minimum of 20 natural teeth, aged 18 to 65 years, willing and physically able to carry out all study procedures, available for all visits, and a plaque score  $\geq 1.8$  after refraining from oral hygiene for  $24 \pm 3$  hours at screening in Visit 1. Subjects were ineligible if they did not meet the inclusion criteria explained in the study protocol.

**Study Treatments.** After enrollment, subjects were randomized and assigned to either a Sonicare Elite 9000 (E Series standard brush head) or a Sonicare FlexCare toothbrush (ProResults standard brush head). Devices were verified for proper function and the easy-start ramp-up mode was inactivat-

Figure 1—Study flowchart



The letters A and B indicate treatment sequences. Bold arrows represent treatments. Changeover of treatments was at visit 2, after the postbrushing examination. Activities at each visit are listed below the respective visit box.

No OH 24 hrs = no oral hygiene was performed for 24 hours; AE = adverse event; TMQH = Turesky Modified Quigley-Hein plaque index.

Table 1—Sample demographics (N = 87)

<b>Age (years)</b>	
Mean $\pm$ SD	38.2 $\pm$ 11.57
Median	38
Range	19–64
<b>Sex</b>	
Women	61 (70.1%)
Men	26 (29.9%)
<b>Hand typically used for brushing</b>	
Both	2 (2.3%)
Left	5 (5.7%)
Right	80 (92.0%)
<b>Number of teeth per subject</b>	
Mean $\pm$ SD	27.2 $\pm$ 1.39
Median	28
Range	24–28
<b>TMQH plaque score (visit 1)</b>	
Mean $\pm$ SD	3.10 $\pm$ 0.53
Median	3.17
Range	1.86–4.37

SD = standard deviation; TMQH = Turesky Modified Quigley-Hein plaque index.

ed. Each subject received a tube of Crest Cool Mint Gel toothpaste.<sup>a</sup> No other oral hygiene measures were permitted during the study. Subjects were requested to brush at home twice per day for 2 minutes using the materials provided. They received brushing instructions and a diary to record compliance with an explanation on its use. To conclude the instruction session, subjects demonstrated their understanding of the directions by brushing with their assigned device in the presence of the instructor.

Subjects used the device for a 6-day familiarization phase. They then refrained from brushing for 24  $\pm$  3 hours before returning to the clinic for the examinations and supervised 2-minute test brushing listed in Figure 1. All toothbrushes were supplied with new brush heads before the brushing episodes.

**Study End Points.** The primary efficacy measure was percent plaque reduction. Using the TMQH,<sup>10</sup>

<sup>a</sup>Procter & Gamble Co; Cincinnati, OH.

per-subject average scores were computed and percent reduction was calculated per subject.

**Clinical Assessment.** On presentation to the clinic at visits 2 and 3 (Figure 1), each subject received an intraoral examination, followed by a full-mouth plaque assessment using the TMQH. Plaque was disclosed and recorded at 6 sites per tooth on a scale of 0 to 5 to determine the prebrushing score. This procedure was repeated after the supervised 2-minute efficacy brushing and resulted in the postbrushing scores. All clinical assessments were made by the same calibrated examiner who was blinded to the treatment assignments. Reliability tests based on repeated grading of plaque scores were undertaken before the study and resulted in an excellent agreement ( $\kappa > 0.75$ ).

**Safety Assessment.** Safety parameters included any adverse changes in the medical or dental status of the subject. The integrity of the oral mucosa was verified at the oral soft tissue examinations.

**Statistical Analysis.** The study was designed to compare the efficacy of 2 powered toothbrushes in removing plaque. The sample size was estimated based on data available from pilot studies. For a crossover design, a minimal difference between the treatment groups of 4%, an assumed within-subject standard deviation of 12%, and a 2-sided  $\alpha = 0.05$  level, a sample size of 80 subjects provided at least 80% power to detect a difference between treatment groups.

The primary analysis was carried out on an intention-to-treat (ITT) basis. To qualify for inclusion, subjects were required to participate at all examinations, have complete pre- and postbrushing data, and comply with study instructions. Subjects were grouped according to the randomized treatment assignment. No correction to nominal *P* values was made for secondary and supplementary efficacy end points. The statistics for continuous variables included number of subjects, mean, and standard deviation. For categorical variables, numbers and percentages of events were computed.

Mean overall plaque scores were treated as con-

Table 2—Summary results for primary study end point (% reduction in TMOH scores; mean  $\pm$  SD; N = 87)

Parameter	Elite 9000	FlexCare	P Value*
Overall	37.35 $\pm$ 13.97	40.57 $\pm$ 14.48	.0039
Anterior region	42.40 $\pm$ 17.18	46.86 $\pm$ 18.21	.0013
Posterior region	34.21 $\pm$ 13.74	36.73 $\pm$ 14.14	.0182
Interproximal surfaces	33.29 $\pm$ 13.62	37.36 $\pm$ 14.46	.0003
Posterior interproximal surfaces	30.52 $\pm$ 13.46	33.45 $\pm$ 14.11	.0082

\**P* values obtained from ANOVA *F* tests based on a mixed effects model.

TMQH = Turesky Modified Quigley-Hein plaque index; SD = standard deviation; ANOVA = analysis of variance.

tinuous variables. Analysis of the primary end point, including parameter and confidence interval estimation, was accomplished using statistical software S-Plus 7.0.<sup>6</sup> The repeated measures crossover data were analyzed using a linear mixed effects model.<sup>30</sup> Subject mean plaque scores obtained by averaging overall sites corresponding to a single subject on a given visit defined the computational unit in statistical tests. Comparisons between groups were performed using the appropriate F test. Analyses were carried out for full mouth, anterior region, posterior region, interproximal sites, and interproximal sites of posterior region.

### Results

Two of the 89 subjects initially enrolled were lost to follow-up. The 87 subjects who completed the study and qualified for the ITT analysis constitute the study sample discussed below. Study population demographics are shown in Table 1. Subjects exhibited moderate-to-high average plaque scores (median TMQH, 3.17) at the screening visit after a 24-hour abstinence from oral hygiene.

Efficacy data for the primary outcome variable (overall percent reduction) and information obtained on subcategories are presented in Table 2 and Figure 2. Subjects using the Sonicare FlexCare model achieved a statistically significantly greater

<sup>6</sup>S-Plus version 7.0, Insightful Corporation, Seattle, WA.

percent reduction ( $P = .0039$ ) in full-mouth TMQH scores than Elite 9000 users. A similar outcome was observed in the anterior region ( $P = .0013$ ), posterior region ( $P = .0182$ ), interproximal surfaces ( $P = .0003$ ), and posterior interproximal surfaces ( $P = .0082$ ). With both devices, the largest plaque score reduction was observed in the anterior region, which includes canines and incisors.

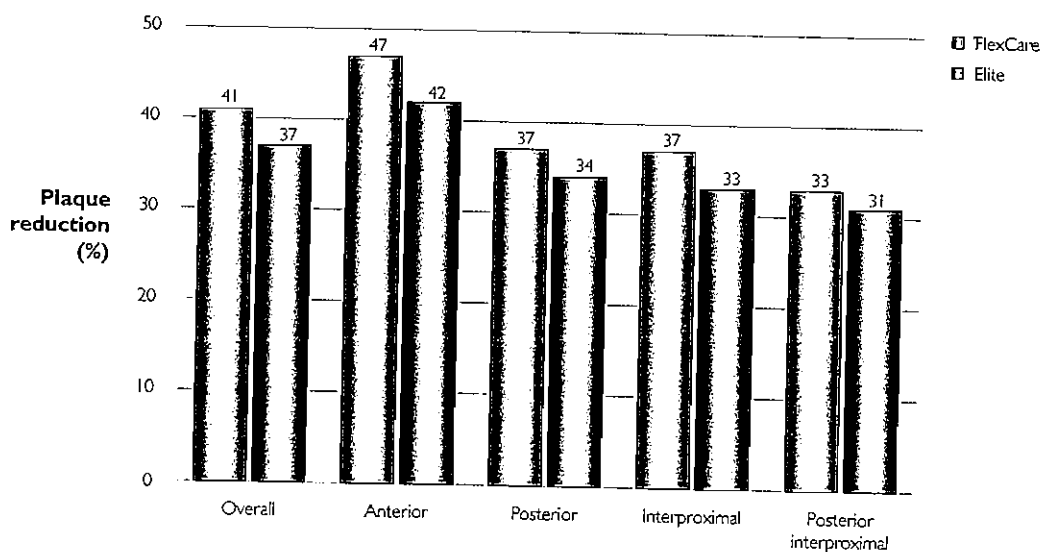
Treatment effect estimates presented in Figure 3 confirm that the Sonicare FlexCare model was more effective in reducing plaque score than the Sonicare Elite 9000. The largest effects were seen in the anterior region (4.5%) and at interproximal surfaces (4.1%). The effect was somewhat smaller in the posterior region, which includes all bicusps and molars (2.5%). All effect estimates were statistically significant favoring Sonicare FlexCare over Sonicare Elite.

The only dental adverse event reported during the study concerned a gingival abrasion in a subject assigned to the Sonicare Elite 9000. The examiner determined that it was possibly related to treatment and mild in severity. The lesion resolved spontaneously within 6 days.

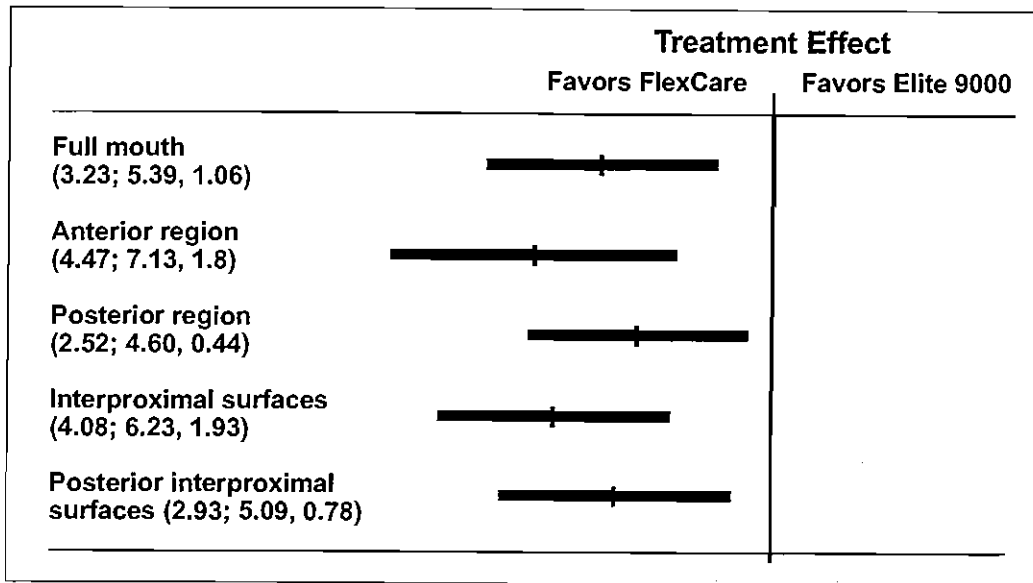
### Discussion

The present study provides the first published clinical evidence that the new Sonicare FlexCare toothbrush is highly effective in reducing dental

Figure 2—Percentage reduction of Turesky Modified Quigley-Hein (TMQH) plaque index scores



The bars represent mean percent TMQH score reduction ( $100\% \times [(prebrushing\ score - postbrushing\ score)/prebrushing\ score]$ ).

**Figure 3**—Estimated treatment effects shown as means and 95% confidence intervals (CIs)

Values are provided in parentheses (mean; upper limit of CI, lower limit of CI). The vertical black line indicates no effect in favor of either treatment. Data located on the left side of the zero effect line indicate that the effect is in favor of Sonicare FlexCare.

plaque biofilm. The cleaning performance of the new device was superior to the well-established Sonicare Elite 9000, as shown in statistically significantly greater treatment effects for all regions of the dentition investigated. Only 1 adverse event was reported during the entire trial, suggesting that both power toothbrushes are safe products.

The spatial relation and number of tufts on the head plate of the new Sonicare ProResults brush head, as well as the characteristics and number of filaments, are identical with those used on Sonicare Elite 9000, except for the new model's improved radial trim and tufting design. This radial design may have resulted in a greater filament reach, thus contributing to the generally improved plaque removal.

In addition to the brush head design, other distinctive modifications of the new toothbrush may have also added to the superior performance of the Sonicare FlexCare. For example, it is equipped with a new drivetrain. Based on the same physical principles as its predecessor, the new motor drives the brush head to slightly greater amplitude and maintains it over a wider load range. This contrasts to previous Sonicare toothbrushes that exhibited a drop in amplitude on loads exceeding a 150-g force. In addition and more obvious to the user are design changes made to the new handle. It is slimmer and lighter, resulting in 30% less volume than the Sonicare Elite 9000. In a consumer acceptance study (data on file), independent consumers reported the Sonicare

FlexCare prototype possessed excellent in-mouth attributes. More specifically, they preferred Sonicare FlexCare to the Elite 9000 for improved maneuvering; access to posterior dentition; and a cleaner, more polished feeling to their teeth. They also liked the handle's fit, size, and balance. Although no effort was made in the present study to determine the individual effect of each of these factors, it is safe to assume that most of these changes contributed to the observed increased efficacy.

The present clinical study compared 2 sonic toothbrushes, the Sonicare Elite 9000 and Sonicare FlexCare. Of these, the former has been evaluated in many studies<sup>23,24</sup> and found to be an effective aid in the daily management of oral hygiene. Typically, such studies last 3 weeks or longer, which is certainly indicated if the objective is to assess plaque-induced oral health outcomes or the long-term safety of a product. The focus of the present study, however, was whether the 2 test products differed in their ability to reduce dental plaque biofilm. The single-use protocol, as applied here, provides a clear answer. Its selection among many design choices is further supported by a published consensus report on the role of mechanical dental plaque removal in prevention of and therapy for caries and periodontal diseases.<sup>25</sup>

### Conclusion

The Sonicare FlexCare power toothbrush was found to be safe and effective. In this randomized,

single-use trial, it reduced plaque scores significantly more than its predecessor, the Sonicare Elite 9000. The largest treatment effects were observed on anterior teeth, closely followed by interproximal surfaces.

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# A Randomized, Single-use Study to Compare Plaque Removal Ability of Sonicare FlexCare and Oral-B Triumph Professional Care 9000

## Abstract

The plaque removal ability of a new sonic toothbrush, the Sonicare FlexCare, was compared with the Oral-B Triumph Professional Care 9000 rotating-oscillating power toothbrush, in a single-use, examiner-blinded, crossover clinical trial. The Turesky Modified Quigley-Hein (TMQH) plaque index was used for efficacy measurements. A TMQH score  $\geq 1.8$  at screening after 24 hours of oral hygiene abstinence was required for inclusion in the study. At Visit 1, qualifying subjects received their assigned toothbrush and toothpaste and were instructed to use them twice daily for 2 minutes during the 7  $\pm$  1-day familiarization phase. Subjects refrained from oral hygiene for 24 hours before Visit 2. At Visit 2, TMQH scores were appraised before and after a 2-minute supervised brushing episode and the second test product was issued. Familiarization, plaque accumulation, and clinical examinations were the same for both study periods. Percent reduction in overall plaque score was the primary efficacy measure. The statistical data analysis used a linear mixed effects model approach. Comparisons between treatment groups were performed using F tests. The safety analysis was based on reported adverse events and oral examinations performed at Visits 2 and 3. The study was completed by 91 subjects. The sample's mean (standard deviation) TMQH score at Visit 1 was 3.45 (0.58). Full-mouth TMQH prebrushing scores were 2.55 (0.76) for FlexCare and 2.81 (0.69) for Triumph. Brushing reduced the scores by 66.5% (13.0) and 60.1% (13.8) for FlexCare and Triumph, respectively. The mean percentages were significantly different ( $P < .0001$ ). Reductions of similar size were observed for the subregions, including anterior, posterior, interproximal, and interproximal posterior sites.



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Dental plaque biofilms are involved in the etiology of the most prevalent oral afflictions: gingivitis, periodontitis, and caries.<sup>1</sup> Effective management of the amount and composition of these biofilms is necessary to achieve oral health and can often be accomplished through regular mechanical plaque disruption and removal. Daily oral hygiene routines that include brushing with fluoride-containing toothpaste and using dental floss are the most frequently recommended methods to remove supragingival plaque.<sup>2</sup>

Both manual and powered toothbrushes are suitable to assist in plaque management.<sup>3</sup> More and more evidence is accumulating that powered toothbrushes are superior to manual toothbrushes in the removal of supragingival plaque.<sup>4</sup> An argument in favor of powered toothbrushes is that they require less manual dexterity. Clinical studies of the most popular power toothbrushes have shown that they are safe for daily use.<sup>5,9</sup> In addition, they might be less harmful to soft and hard tissues because less pressure is applied and horizontal brushing is avoided by users.<sup>10,11</sup>

Presently, the most obvious differentiating feature

among power toothbrushes is the brush head motion. Most products can be defined as having either a rotating-oscillating or a high-frequency, high-amplitude sweep (sonic) brush head motion. Recently, a new generation of products has been developed. For example, the Sonicare FlexCare<sup>a</sup> (FlexCare) represents a new platform of sonic toothbrushes. It is smaller and lighter than its predecessor Sonicare Elite,<sup>a</sup> has a simple mechanical snap-on/snap-off brush head-to-handle interface, and features the ProResults brush head with radial trim. A clinical study showed FlexCare with the ProResults radial brush head removes plaque better than the Sonicare Elite.<sup>12</sup> Similarly, the Oral-B Triumph Professional Care 9000<sup>b</sup> (Triumph) is a new model in the oscillating-rotating line of power toothbrushes. As new power toothbrushes are marketed to the public, it is important that dental professionals have information available that allows them to understand the advantages and disadvantages of various products, especially with regard to clinical performance. Therefore, the purpose of this clinical study was to compare the plaque removal ability of the FlexCare and Triumph power toothbrushes.

## Materials and Methods

### General Study Information and Design

This 2-week, examiner-blind, randomized, cross-

<sup>a</sup>Philips Oral Healthcare, Inc; Snoqualmie, WA  
<sup>b</sup>Procter & Gamble Co; Cincinnati, OH.

over study was executed at Dentres BV, Nijmegen, the Netherlands, an independent clinical research organization, and compared the efficacy of 2 power toothbrushes. The study protocol and subject consent form were approved by the Independent Review Board, Nijmegen. The study was conducted in agreement with the Good Clinical Practice Guidelines of the International Conference on Harmonization.<sup>13</sup>

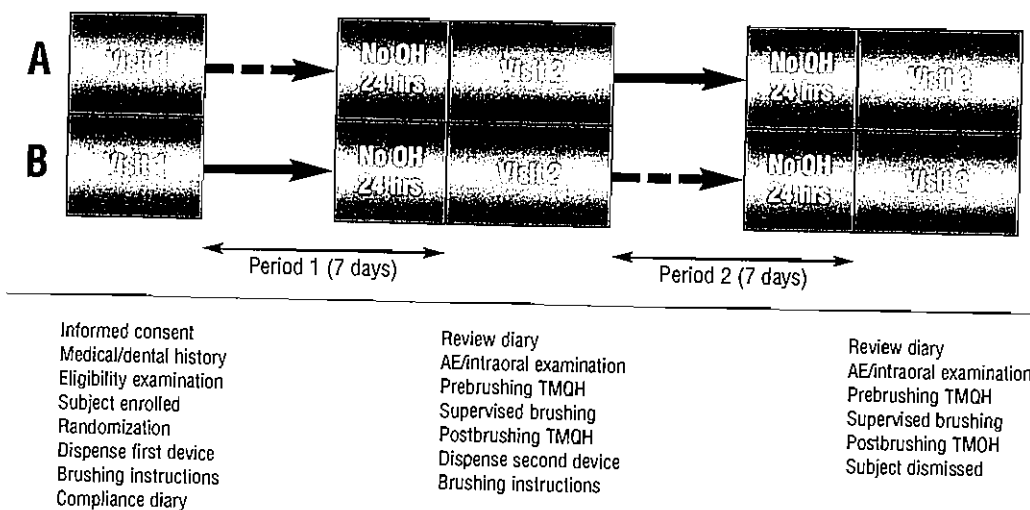
Study activities and a timeline are shown in Figure 1. Subjects used each assigned device during a  $7 \pm 1$ -day familiarization phase at home. Before they returned to the clinic on day 7, subjects refrained from any oral hygiene measures for  $24 \pm 3$  hours.

### Subjects and Test Products

Each potential participant was required to read, sign, and date the consent form. To qualify for the study, subjects had to be nonsmokers with at least 20 natural teeth, 18 to 65 years old, willing and physically able to carry out all study procedures, and available for all visits. Subjects were also required to have a Turesky Modified Quigley-Hein (TMQH) plaque index score<sup>14</sup>  $\geq 1.8$  after refraining from oral hygiene for  $24 \pm 3$  hours before Visit 1. Subjects with moderate-to-severe chronic periodontal disease, with need for or currently undergoing dental treatment, or exhibiting serious medical conditions were excluded.

Subjects were randomized to 1 of 2 treatment sequences, A  $\rightarrow$  B or B  $\rightarrow$  A. Treatment consisted of using either the FlexCare with the ProResults radial

Figure 1—Study flowchart



The letters A and B indicate treatment sequences. Changeover of treatments was at visit 2, after the postbrushing examination. No OH 24 hrs = subjects refrained from oral hygiene for 24 hours; AE = adverse event; TMQH = Turesky Modified Quigley-Hein plaque index.

Table 1—Summary of subject characteristics (N = 91)

Characteristic	
<b>Age (years)</b>	
Mean ± SD	23.5 ± 6.8
Median	22
Range	18–53
<b>Sex</b>	
Women	70 (76.9%)
Men	21 (23.1%)
<b>Hand typically used for brushing</b>	
Left	6 (6.6%)
Right	85 (93.4%)
<b>Number of teeth per subject, as used in the analysis</b>	
Mean ± SD	27.6 ± 0.91
Median	28
Range	24–28
<b>TMQH plaque score (visit 1)</b>	
Mean ± SD	3.45 ± 0.58
Median	3.55
Range	1.89–4.41

SD = standard deviation; TMQH = Turesky Modified Quigley-Hein plaque index.

brush head or the Triumph power toothbrush with the FlossAction brush head in random sequence. The easy-start ramp-up mode of the FlexCare was inactivated. Subjects also received a sufficient supply of Prodent Soft Mint fluoride (1,450 ppm) toothpaste.<sup>c</sup> No other oral hygiene measures were permitted during the study.

At Visits 1 and 2, all subjects received detailed brushing instructions. At the conclusion of the instruction session, subjects demonstrated their understanding of the directions by brushing with the assigned device in the presence of the instructor. Home use of the test material was restricted to 2 mandatory 2-minute brushing sessions per day.

#### Clinical Assessment

On presentation at the clinic, each subject received an intraoral examination, followed by the full-mouth plaque assessment using the TMQH.

<sup>c</sup>Sara Lee; Amersfoort, the Netherlands.

Plaque was disclosed with Dentorama Blue Disclosing Pellets Pro 155<sup>d</sup> and graded at 6 sites per tooth on a scale of 0 to 5. This procedure was repeated after the subject's supervised 2-minute test brushing to determine the postbrushing scores. Efficacy brushings at both visits were done using fully charged handles provided with new brush heads. All clinical assessments were made by the same experienced and calibrated examiner.

#### Safety Assessments

Parameters of safety included any adverse changes in the subject's medical or dental status. The integrity of the oral mucosa was verified at the oral soft tissue examinations.

#### Study End Points

The primary efficacy measure was percent plaque reduction ( $100\% \times [(prebrushing\ score - postbrushing\ score)/prebrushing\ score]$ ). The TMQH was used to score surface plaque levels pre- and postbrushing. Average scores and percent reduction were calculated on a per-subject basis. Secondary end points were between-treatment differences of postbrushing TMQH scores, and treatment effects.

#### Statistical Calculations

Sample size was determined assuming a 2-sided  $\alpha = 0.05$  level, standard deviation of 11%, and a cross-over design. A sample of 85 subjects provided 80% power to detect a 3.5% difference between treatments.

The primary analysis was carried out on an intention-to-treat (ITT) basis. No corrections to nominal *P* values were made for secondary and supplementary efficacy end points. The statistics for continuous variables included number of observations, mean, and standard deviation. For categorical variables, numbers and percentages of events were computed.

Mean overall plaque scores and percentages were treated as continuous variables. Analyses of the primary end point including treatment means, confidence intervals (CIs), and hypothesis tests were

<sup>d</sup>Svenska Dentorama; Solna, Sweden.

Table 2—Summary statistics for percent reduction in TMQH score (N = 91)

Parameter (mean ± SD; <i>P</i> < .0001*)	FlexCare	Triumph
Overall	66.47 ± 13.04	60.13 ± 13.75
Anterior region	80.30 ± 15.19	72.54 ± 15.83
Posterior region	59.05 ± 14.72	52.78 ± 14.78
Interproximal surfaces	67.55 ± 12.16	61.48 ± 13.30
Posterior interproximal surfaces	59.04 ± 14.14	53.09 ± 14.37

\**P* values obtained from ANOVA *F* tests based on a mixed effects model.

TMQH = Turesky Modified Quigley-Hein plaque index; SD = standard deviation; ANOVA = analysis of variance.

conducted and conclusions drawn using a linear mixed effects model for repeated measures crossover studies. Subject mean plaque scores obtained by averaging overall sites corresponding to a single subject on a given visit defined the computational unit in statistical tests. Comparisons between groups were performed using the overall F test of analysis of variance. Analyses were carried out for full mouth, anterior region, posterior region, interproximal sites, and interproximal sites of the posterior region.

## Results

Of the 92 subjects screened for the study, one subject was disqualified because of a low plaque score at the screening visit. All qualified 91 subjects were included in the ITT analysis. Sample demographics are shown in Table 1. Study subjects exhibited moderate-to-high average plaque scores (range, 1.89-4.41) at the screening visit and were users of manual toothbrushes. Excellent compliance with the prescribed home procedures was reported by virtually all subjects. During the first period, FlexCare and Triumph users brushed  $13.2 \pm 0.47$  and  $13.3 \pm 0.72$  times, respectively. This high level of compliance was maintained during the second period.

Efficacy data for the primary outcome variable and additional information obtained from subregions are listed in Table 2 and Figure 2. Subjects using FlexCare achieved a statistically significantly greater percent reduction ( $P < .0001$ ) in full mouth (overall)

TMQH scores than Triumph users. Similar outcomes favoring FlexCare were observed for the anterior region ( $P < .0001$ ), posterior region ( $P < .0001$ ), interproximal surfaces ( $P < .0001$ ), and posterior interproximal surfaces ( $P < .0001$ ). With both devices, the largest percent plaque score reductions were observed in the anterior region (FlexCare, 80.3%; Triumph, 72.5%).

The secondary end points further support the findings. FlexCare users had lower overall mean postbrushing plaque scores than users of Triumph ( $0.86 \pm 0.45$  vs  $1.14 \pm 0.53$ ;  $P < .0001$ ). Similar results were obtained for all subregions. Treatment effect estimates and 95% CIs for percent change in plaque scores are presented in Figure 3. They show a 6.34% (95% CI; 4.03%-8.64%) effect in favor of FlexCare. The largest treatment effect was seen on anterior teeth (7.75%; 95% CI; 4.94%-10.57%). Other treatment effects investigated for subregions were smaller but still significant at the 5% significance level.

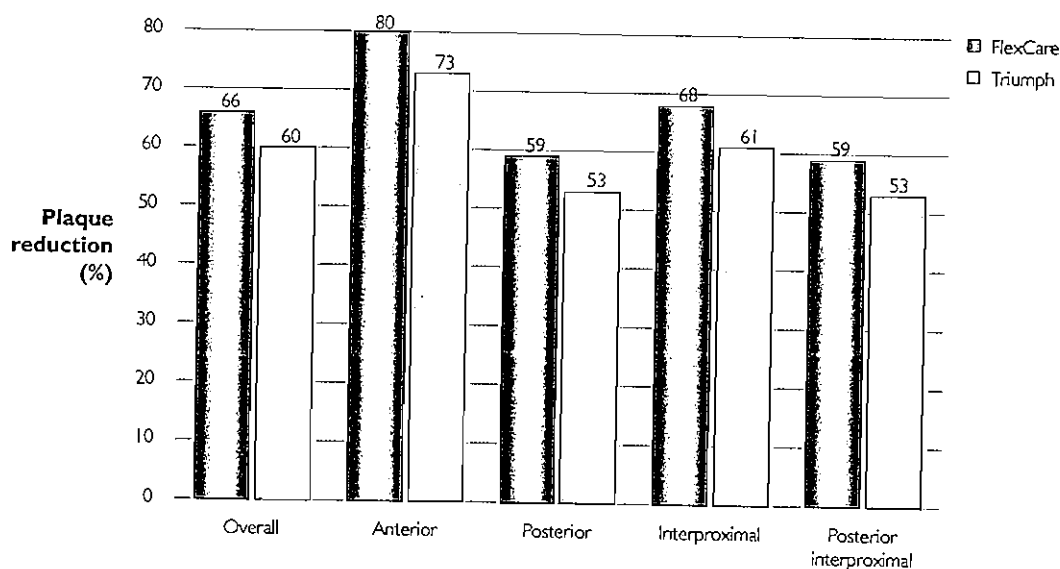
## Adverse Events

Intraoral examinations at each visit and review of subject-reported adverse events demonstrated the safety of the tested products with respect to hard and soft tissues.

## Discussion

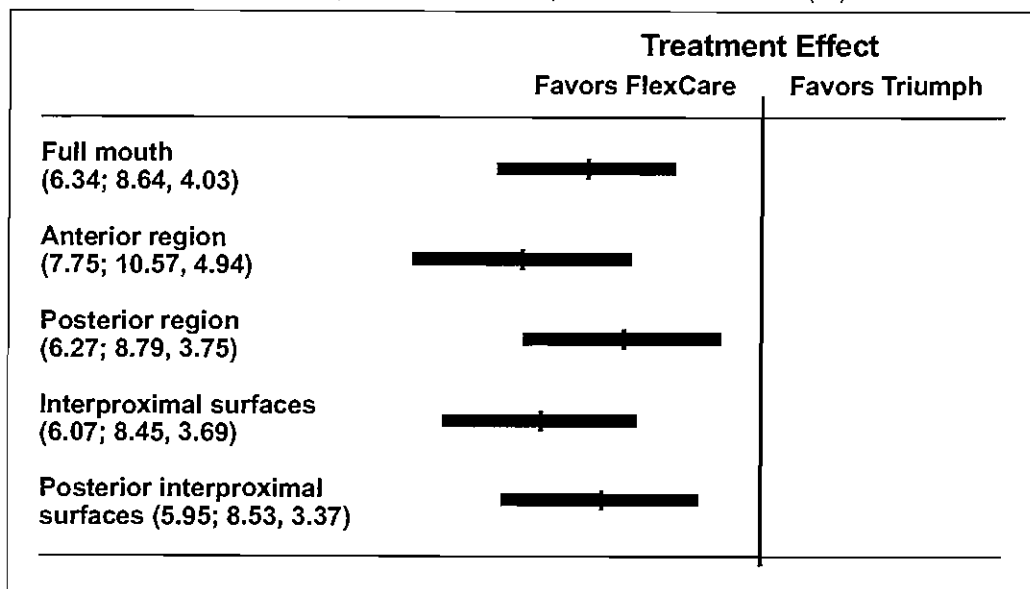
The present study provides clinical evidence that modern power toothbrushes are highly effective

Figure 2—Percentage reduction of Turesky Modified Quigley-Hein plaque index scores



The bars represent mean percent TMQH score reduction ( $100\% \times [\text{prebrushing score} - \text{postbrushing score}] / \text{prebrushing score}$ ).

Figure 3—Estimated treatment effects are presented as means and respective 95% confidence intervals (CIs)



Values are provided in parentheses (mean; upper limit of CI, lower limit of CI). The vertical black line indicates no effect in favor of either treatment. Data located on the left side of the zero effect line indicate that the effect is in favor of FlexCare.

in removing supragingival plaque in periodontally healthy adult subjects. In this trial, FlexCare was significantly more effective than Triumph. The benefits were demonstrated by greater percent plaque score reduction, lower postbrushing plaque scores, and treatment effects in favor of FlexCare. Superior plaque reduction was found both overall and in all subregions of the dentition. Importantly, there were no reports of untoward product-inflicted soft or hard tissue injury, corroborating the robust safety record of previous sonic products.<sup>15-17</sup>

A single-use model was used to investigate plaque removal efficacy. The approach is recommended for assessing an ideal situation in which all subjects comply with the use of the device to which they are randomly assigned.<sup>18,19</sup> Therefore, the reduction in plaque score achieved with both devices represents an optimum outcome. However, because results obtained from a single-use study do not automatically translate into clinically relevant benefits, such as improvement of gingival or periodontal health, these and other clinical outcomes must be determined in long-term, randomized controlled clinical trials of the products.

Our results suggest greater efficacy for the sonic power toothbrush than Triumph, which features a rotating-oscillating brush head motion. The favorable outcome may be explained by enhancements in the new toothbrush platform. These changes in architecture and design were aimed at increasing plaque

removal efficacy and consumer experience. Most obvious, the FlexCare handle is slimmer and lighter than the Triumph handle, which may improve maneuverability and reach. The ProResults brush head was modified so that the 2 exterior tuft columns were positioned at a slight angle projecting away from the next interior tuft columns and the bristles trimmed to a dome shape. This so-called radial bristle arrangement resulted in wider filament reach during the brush head's sweeping motion. Thus, the FlexCare brush head, which is also considerably slimmer than the Triumph brush head, combined with its smaller handle, may result in increased accessibility to hard-to-reach areas. Lastly, the toothbrush features a new drivetrain that maintains bristle amplitude over a wider load range than Elite or Advance models.<sup>20</sup> Amplitude is relevant in this context because it determines the contact area of the bristles with the tooth surface and the strength of fluid dynamic action.<sup>21</sup>

Intraoral examinations were conducted to review the integrity of oral soft and hard tissues at all visits before subjects started the 2-minute efficacy brushing. No attempt was made to visualize and count gingival abrasions or other mucosal lesions immediately after these supervised brushings. The tissue examination results reflected events that occurred during the home-use periods. Seven adverse events were classified as definitely product related and occurred in subjects using the Triumph

brush. Six patients reported painful gingiva at the beginning of the second study period. However, because there was no noticeable tissue injury observed at the visit 3 oral examination, it is possible that the lesions were a result of the change from one product to the other and not inherent to a product deficiency.

### Conclusion

In this randomized, single-use clinical study, the Sonicare FlexCare and the Oral-B Triumph power toothbrushes were found to be safe and effective. FlexCare reduced plaque scores significantly more than Triumph, with the largest treatment effects observed on anterior teeth.

### Acknowledgments

The authors wish to thank Monique Oliemeulen, Study Coordinator (Dentres BV, Nijmegen, the Netherlands), Matt Johnson, Senior Statistician (Philips Oral Healthcare, Inc), and Jinling Wei, Statistician (Philips Oral Healthcare, Inc) for their excellent work. The help of Dr. Arthur Hefli (Sammamish, WA) and Ms. Rita Shafer (Shafer Editorial Services, Chicago, IL) with the preparation of this manuscript is gratefully acknowledged. The study was sponsored by a grant from Philips Oral Healthcare, Inc, Snoqualmie, WA.

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# A Randomized, Parallel-design Study to Compare the Effects of the Sonicare FlexCare and the Oral-B P40 Manual Toothbrush on Plaque and Gingivitis

## Abstract

Effects on plaque removal and plaque-induced gingival inflammation of a new sonic toothbrush, Sonicare FlexCare (FlexCare), and a manual toothbrush were evaluated in a randomized, single-masked, controlled clinical trial. One hundred seventy-nine subjects with gingival index (GI) scores  $\geq 2.0$  at  $\geq 20$  sites and plaque index (PI) scores  $\geq 0.8$  were randomly assigned to receive the FlexCare power toothbrush or the Oral-B P40 control manual toothbrush. After 2 and 4 weeks of using the product at home twice daily for 2 minutes, efficacy was assessed with the Loe and Silness GI and the Silness and Loe PI. Percent change in GI score between baseline and 4-week visit was the primary efficacy variable. Secondary outcomes included change in PI scores and number of bleeding sites. Safety was appraised using adverse event reports and soft tissue examinations. Statistical analyses were performed using a linear mixed effects model and treatments were compared using appropriate F tests. One hundred seventy-five subjects (87 FlexCare users, 88 manual toothbrush users) completed the study. Mean ( $\pm$  standard deviation) GI scores at baseline were  $1.45 \pm 0.14$  and  $1.42 \pm 0.15$  for the FlexCare and manual toothbrushes, respectively. The 4-week study period resulted in significant reductions of GI and PI scores from baseline ( $P < .0001$ ) for both brushes; the between-group difference in the change in number of bleeding sites was 3.7 in FlexCare's advantage ( $P = .029$ ). In addition, a significant treatment effect favoring FlexCare over a manual toothbrush was observed for overall percent PI score reduction ( $P = .015$ ) over 4 weeks. Similar statistically significant treatment effects in favor of FlexCare were observed for all subregions. Product safety was confirmed. In conclusion, FlexCare was significantly more effective in plaque and bleeding reduction than a manual toothbrush after 4 weeks.



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The landmark studies of Loe and colleagues<sup>1</sup> established the fundamental relationship between dental plaque and gingival inflammation. Subsequent studies<sup>2</sup> concluded that plaque-induced gingivitis affects people irrespective of age, socioeconomic status, race, or ethnicity, and that a high prevalence of gingivitis can be found in most populations.<sup>3</sup> Clinically, gingivitis is characterized by changes in tissue color, size, shape, consistency, and its full reversibility on elimination of etiology.<sup>4</sup> If untreated, however, plaque-induced gingivitis can progress to further periodontal destruction in a subset of the adult population.<sup>5</sup> Hence, elimination of chronic gingival inflammation is crucial for the prevention of both gingivitis and periodontitis.

Plaque control is the most effective way to avoid gingival inflammation. It has been reported that twice-daily toothbrushing plus interdental cleaning can prevent the development of gingivitis.<sup>6</sup> However, it has been speculated that preventing oral diseases

might be related more to how well oral hygiene is executed rather than how frequently it is performed.<sup>7</sup> Nevertheless, daily oral hygiene routines that include toothbrushing with fluoride-containing toothpaste and the use of dental floss, as well as regular visits to the dentist and a well-balanced diet, are currently recommended by the American Dental Association<sup>8</sup> as methods of choice to remove supragingival plaque and maintain oral health.

According to a recent systematic literature review,<sup>9</sup> there is growing evidence that powered toothbrushes are better than manual toothbrushes in removing supragingival plaque. Powered toothbrushes are less demanding of the average user's manual dexterity skill, which could improve compliance with professional recommendations.<sup>10</sup> Hence, it can be postulated that using a powered toothbrush could lead to improved oral health.

In recently executed single-use efficacy studies,<sup>11,12</sup> the new Sonicare FlexCare<sup>®</sup> power toothbrush showed excellent plaque removal ability. However, single-use tests of oral health care products cannot be used to draw conclusions regarding potential long-term benefits. This issue was addressed in the present 4-week, single-blinded, randomized clinical trial. Its objective was to determine the effects of twice-daily toothbrushing with the Sonicare FlexCare (FlexCare) and the Oral-B P40 manual toothbrush<sup>b</sup> as the control on plaque-induced gingival inflammation and plaque scores.

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<sup>b</sup>Procter & Gamble Co; Cincinnati, OH.

## Materials and Methods

### General Study Information and Design

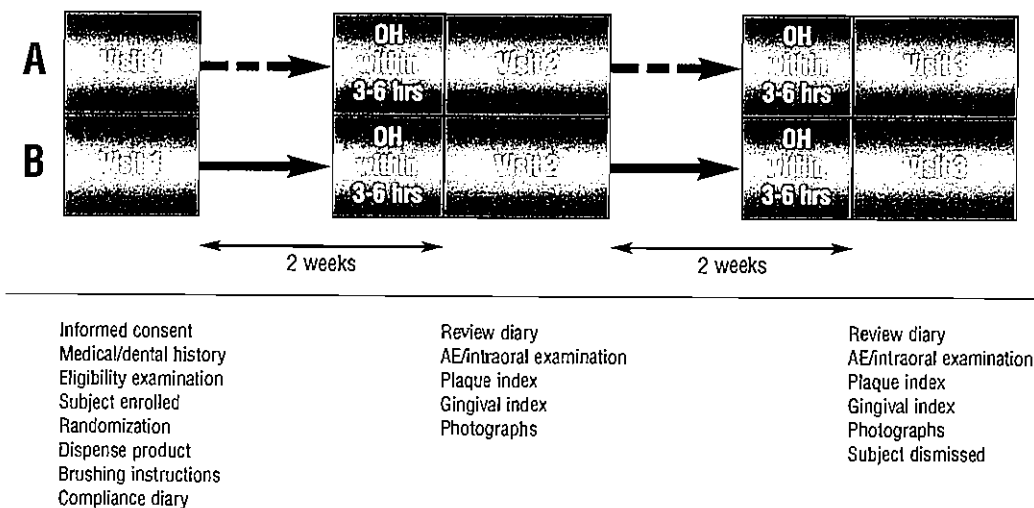
The study was executed at 4-Front Research Ltd, Cheshire, United Kingdom, an independent clinical research organization. The study was conducted in agreement with the Good Clinical Practice Guidelines of the International Conference on Harmonization,<sup>13</sup> with protocol and consent forms approved by the Independent Ethics Committee of 4-Front Research.

Activities and a timeline of the parallel-arm, 4-week study are presented in Figure 1. Brushes and toothpaste were distributed at visit 1 (baseline), with visits 2 and 3 scheduled after 14 and 28 days of product use.

**Subjects.** Eligible subjects were between 18 and 65 years old, willing and physically able to carry out all study procedures, available for all visits, non-smokers, and with at least 20 natural teeth. They were required to have a gingival index (GI)<sup>14</sup> score of  $\geq 2.0$  on at least 20 sites and a plaque index (PI)<sup>15</sup> score of  $\geq 0.8$  after refraining from oral hygiene for 3 to 6 hours before visit 1. Candidates with severe gingivitis (overall mean GI  $\geq 2.5$ ), moderate-to-severe chronic periodontal disease, need for or currently undergoing dental treatment, or exhibiting serious medical conditions were excluded.

**Study Treatment.** Subjects were randomized to receive either the FlexCare power toothbrush or the Oral-B P40 manual toothbrush. Each FlexCare was checked for proper function and the easy-start mode was inactivated. Subjects also received a supply of Crest Cool Mint Gel toothpaste.<sup>b</sup> No other oral

Figure 1—Study flowchart



The letters A and B indicate treatments. Activities executed at each visit are listed below the respective visit box.

AE = adverse events were recorded; OH within 3-6 hrs = subjects were required to brush their teeth 3 to 6 hours before clinic visits.

hygiene measures were allowed during the study.

At visit 1, subjects received detailed brushing instructions. Home use of the devices was restricted to 2 mandatory 2-minute brushings per day. Subjects also received a diary to record compliance and demonstrated their understanding of the directions by brushing with their assigned device in the presence of the instructor.

**Study Objectives.** The primary efficacy measure was percent change from baseline in overall GI score after 4 weeks of product use. The following secondary outcomes were also assessed: change in overall PI, change in the number of bleeding sites, and comparisons between treatments.

**Clinical Assessment.** Subjects brushed their teeth 3 to 6 hours before they attended the clinic at baseline and on days 14 and 28. Plaque and gingivitis were scored on all available natural teeth at 4 sites per tooth.<sup>14,15</sup> A bleeding site was defined as a site scored GI  $\geq 2.0$ . Clinical assessments were made by the same calibrated examiner at all 3 visits.

**Statistical Analyses.** Data were entered into a secure, Web-based electronic data capture system. Statistical analyses were performed using SAS.<sup>\*</sup>

The following assumptions were made to estimate sample size: a 2-sided  $\alpha = 0.05$  level test, a standard deviation of 11.5%, and a parallel-arm design. The resulting sample size of 85 subjects per group completing the study provided at least 80% power to detect a 5% difference in GI score between treatments.

Subjects were required to participate in all examinations, complete sets of pre- and postbrushing data, and comply with study requirements. No corrections to nominal *P* values were made for secondary and supplementary efficacy end points. Mean overall GI and PI scores were treated as continuous variables. Analyses of percent change in GI and PI scores, including parameter and confidence interval estimations, were accomplished using separate linear mixed effects models to account for the longitudinal nature of the gingivitis and plaque data collection methods. Analyses of number of bleeding sites were accomplished using analysis of covariance models with adjustments for baseline group differences. Within-group differences were analyzed using the paired *t* test. Subject was always used as the computational unit in statistical tests. Comparisons between groups were performed using the appropriate *F* test.

## Results

Of the 216 subjects screened, 179 met the inclusion criteria and were randomly assigned to a treat-

<sup>\*</sup>SAS Corp; Cary, NC.

Table 1—Sample demographics

Characteristic	FlexCare	Manual toothbrush
<b>Subjects (N)</b>	87	88
<b>Age (years)</b>		
Mean $\pm$ SD	36.8 $\pm$ 8.3	38.6 $\pm$ 10.6
Median	39	38
Range	18–58	18–64
<b>Sex</b>		
Women	71 (81.6%)	71 (80.7%)
Men	16 (18.4%)	17 (19.3%)
<b>Hand typically used for brushing</b>		
Both	4 (4.6%)	3 (3.4%)
Left	11 (12.6%)	7 (8.0%)
Right	72 (82.8%)	78 (88.6%)
<b>Number of teeth per subject</b>		
Mean $\pm$ SD	26.3 $\pm$ 1.9	26.2 $\pm$ 1.8
Median	27	27
Range	21–28	21–28
<b>Silness and Loe plaque index</b>		
Mean $\pm$ SD	1.84 $\pm$ 0.15	1.79 $\pm$ 0.17
Median	1.85	1.80
Range	1.46–2.22	1.15–2.12
<b>Loe and Silness gingival index</b>		
Mean $\pm$ SD	1.45 $\pm$ 0.14	1.42 $\pm$ 0.15
Median	1.43	1.41
Range	1.18–1.90	1.14–2.09
<b>Number of bleeding sites per subject (Loe and Silness<sup>14</sup> gingival index scores <math>\geq 2</math>)</b>		
Mean $\pm$ SD	44.7 $\pm$ 12.4	41.9 $\pm$ 11.9
Median	43	40
Range	25–78	21–85

SD = standard deviation.

ment. Four subjects, 2 in each treatment group, did not complete the study (3 withdrawals, 1 lost to follow-up). Thus, 175 subjects completed the study and were included in the efficacy analysis. Demographic information is presented in Table 1. Briefly, subjects were healthy adults who presented at baseline with mild-to-moderate GI scores (mean  $\pm$  SD, 1.44  $\pm$  0.14) and moderate PI scores (1.82  $\pm$  0.16). A small but statistically significant difference between treatments was observed for baseline PI scores (*P* = .038). Other between-group differences were not significant.

A high level of compliance with study instructions was observed in both groups. Most subjects indicated they always followed study instructions (FlexCare, 90%; manual toothbrush, 85%). The

Table 2—Changes in GI scores after 2 and 4 weeks

Parameter	N	Baseline Mean ± SD	2 Weeks		4 Weeks	
			Change in GI* Mean ± SD	Change in GI* %	Change in GI* Mean ± SD	Change in GI* %
<b>Overall</b>						
FlexCare	87	1.45 ± 0.14	-0.22 ± 0.11	-14.7	-0.41 ± 0.13	-28.4
Oral-B P40	88	1.42 ± 0.14	-0.19 ± 0.10	-13.0	-0.39 ± 0.14	-27.8
P value				.173		.612
<b>Interproximal sites</b>						
FlexCare	87	1.45 ± 0.17	-0.25 ± 0.13	-16.9	-0.41 ± 0.14	-28.1
Oral-B P40	88	1.41 ± 0.19	-0.21 ± 0.14	-14.0	-0.38 ± 0.17	-26.4
P value				.033		.193

\*Changes in GI scores from baseline at 2 and 4 weeks are statistically significant at  $P < .0001$ .  
SD = standard deviation; GI = gingival index.

average brushing frequency was similar in both groups (visit 2,  $P = .343$ ; visit 3,  $P = .121$ ) and reflected twice-daily brushing on average. All subjects confirmed they brushed for 2 minutes as required and observed the 3- to 6-hour brushing requirement before clinic visits.

The results obtained for primary and secondary efficacy measures are shown in Tables 2 through 4 and Figure 2. For both treatment groups, statistically highly significant ( $P < .0001$ ) reductions in overall GI and PI scores were observed between visits 1 and 2 and visits 1 and 3. After 4 weeks, overall GI scores declined by 0.41 (28.4%) and 0.39 (27.8%) (Table 2) for FlexCare and the manual toothbrush, respectively. Similarly, overall PI scores dropped by 0.80 (43.9%) and 0.72 (40.0%) for the FlexCare and manual toothbrushes, respectively (Table 3). The difference in overall PI score between treatment groups at visit 3 was significant at  $P = .002$  (for percent change,

$P = .015$ ). A continuous steep decline in number of bleeding sites was seen over the entire study (Table 4). In the FlexCare group, sites with a GI score  $\geq 2$  at baseline dropped by 31.6 sites compared with 27.9 sites in the manual toothbrush group ( $P = .029$ ), corresponding to 70.6% and 66.6% change, respectively.

The analysis of GI scores did not reveal large differences between treatments or among subregions. An exception was observed at visit 2, when a significant ( $P = .033$ ) treatment effect in favor of FlexCare was observed at interproximal sites (Table 2). In contrast to gingival inflammation, substantial regional variation was reflected in the PI scores assessed after 2 and 4 weeks (Table 3). In particular, treatment effects estimated for regional percent change in PI scores invariably favored FlexCare after 4 weeks (anterior, 3.5%,  $P = .100$ ; posterior, 4.5%,  $P = .002$ ; interproximal, 4.0%,  $P = .020$ ; posterior interproximal, 4.4%,  $P = .007$ ). Intraoral examina-

Table 3—Changes in PI after 2 and 4 weeks

Parameter	N	Baseline Mean ± SD	2 Weeks		4 Weeks	
			Change in PI* Mean ± SD	Change in PI* %	Change in PI* Mean ± SD	Change in PI* %
<b>Overall</b>						
FlexCare	87	1.84 ± 0.15	-0.42 ± 0.16	-22.7	-0.80 ± 0.19	-43.9
Oral-B P40	88	1.79 ± 0.17	-0.36 ± 0.16	-20.3	-0.72 ± 0.22	-40.0
P value				.129		.015
<b>Posterior teeth</b>						
FlexCare	87	1.89 ± 0.14	-0.35 ± 0.16	-18.5	-0.72 ± 0.20	-38.5
Oral-B P40	88	1.85 ± 0.15	-0.31 ± 0.14	-16.9	-0.62 ± 0.20	-33.9
P value				.272		.002
<b>Interproximal sites</b>						
FlexCare	87	1.91 ± 0.14	-0.42 ± 0.19	-22.3	-0.79 ± 0.22	-41.7
Oral-B P40	88	1.85 ± 0.16	-0.35 ± 0.18	-19.1	-0.70 ± 0.24	-37.7
P value				.060		.020

\*Changes in PI scores from baseline at 2 and 4 weeks are statistically significant at  $P < .0001$ .  
PI = plaque index; SD = standard deviation.

Table 4—Change in number of bleeding sites after 2 and 4 weeks

Parameter	N	Baseline Sites	2 Weeks Change in sites	4 Weeks Change in sites
FlexCare	87	44.72 ± 12.35	-24.07 ± 9.15	-31.59 ± 9.33
Oral-B P40	88	41.85 ± 11.91	-21.80 ± 7.57	-27.89 ± 9.06
P value			.324	.029

P value is from ANCOVA.

SD = standard deviation; ANCOVA = analysis of covariance.

tions at each visit and review of subject-reported adverse events demonstrated the safety of the tested products with respect to hard and soft tissues.

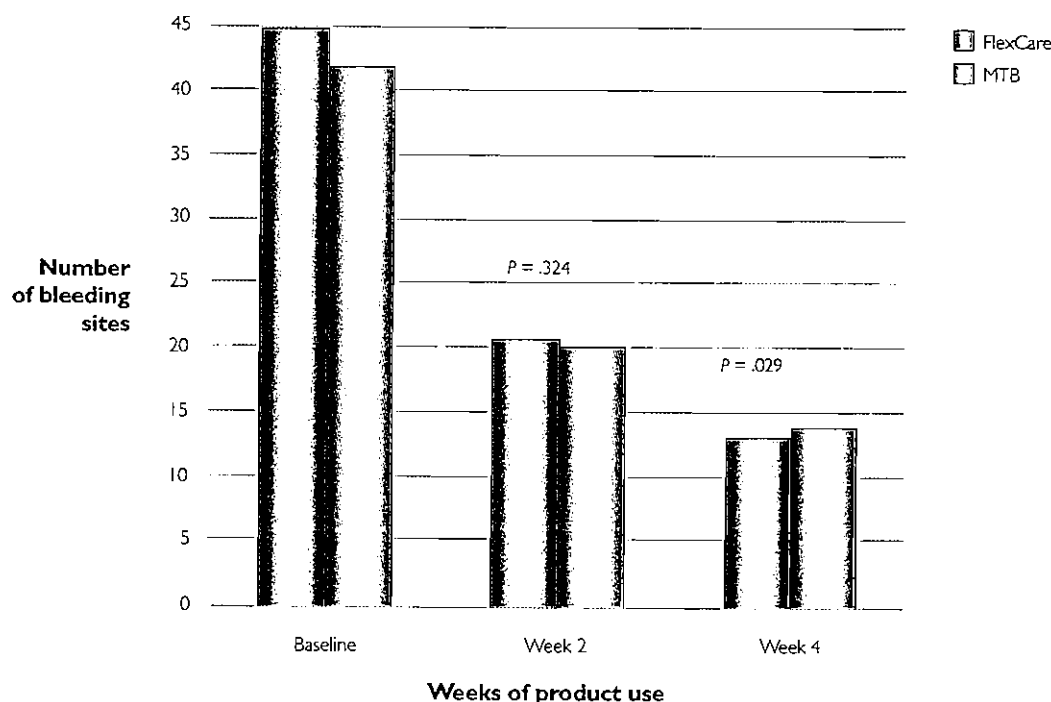
### Discussion

The results from this 4-week clinical trial demonstrate a strong effect of the FlexCare on reducing plaque-induced gingival inflammation. This was reflected in a highly significant reduction of GI scores after 2 and 4 weeks of use. The positive outcome corroborates results obtained in similar studies conducted with other sonic toothbrushes.<sup>16-18</sup> It was further substantiated by significantly reduced PI scores and a drop in the number of bleeding sites by 70.6% over the 4-week period. Reductions in GI and

PI scores were 28.4% and 43.9%, respectively, and associated score reductions between baseline and visit 3 were statistically significant. The results achieved with FlexCare clearly exceeded the efficacy thresholds of 15% for GI and statistical significance for PI established by the American Dental Association Acceptance Program<sup>19</sup> for power toothbrushes.

This study also demonstrates that FlexCare offers statistically significantly greater plaque removal ability than a manual toothbrush. The observed treatment effect of 3.9% probably underestimated the true advantage that could be expected from using the FlexCare in a nontrial situation. For instance, all manual toothbrush users reported excellent compliance with instructions for brushing

Figure 2—Number of gingival sites with GI score ≥2.0 at baseline (bleeding sites) by treatment group



P values were calculated from ANCOVA adjusted for baseline differences.

GI = gingival index; MTB = manual toothbrush; ANCOVA = analysis of covariance.

frequency and duration. This finding might be attributed to the Hawthorne effect<sup>20</sup>; on the other hand, it might be the result of an ideal experimental environment that does not occur in real life. In fact, it has been reported that, on average, persons observed in a noninvasive method spent slightly less than 1 minute cleaning their teeth<sup>21</sup>; individuals also typically overestimated the time they spend toothbrushing by as much as 2-fold on average.<sup>22</sup> Recently, Milleman and colleagues<sup>23</sup> used a concealed video camera to study compliance with toothbrushing instructions in 82 adolescents. They observed a 30% longer brushing time in subjects assigned to a Sonicare power toothbrush equipped with a timer than in subjects using a manual toothbrush without a timer. Similar to the Sonicare used in the Milleman and colleagues study,<sup>23</sup> the FlexCare features an automatic timer that stops the brushing cycle after 2 minutes and indicates elapsed time at 30-second intervals, which helps the user adhere to proper toothbrushing instructions.

A secondary end point of this trial investigated gingival sites that exhibited bleeding on probing at baseline. Keeping in mind the subjectivity of bleeding provocation,<sup>24,25</sup> such sites are easier to identify than subtle changes in tissue color or shape. Figure 2 shows the steep decline in the number of bleeding sites over the study period. It also shows that the gap between the treatment groups increased with study duration. It can be expected that this trend in favor of FlexCare will continue and become more pronounced as the Hawthorne effect fades and the advantages of a power toothbrush take over, resulting in a true oral health benefit.

### Conclusions

The Sonicare FlexCare power toothbrush was effective and safe. In this randomized, 4-week clinical trial, it reduced plaque and gingivitis scores significantly. Significant treatment effects in favor of FlexCare were also observed for overall plaque scores, the posterior region, and interproximal sites. Moreover, FlexCare also statistically significantly reduced the number of bleeding sites ( $P = .029$ ) compared with the manual control.

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# In Vitro Assessment of Toothbrush Wear on Natural and Restorative Materials

## Abstract

This article summarizes 3 in vitro studies investigating the effect of the new Sonicare FlexCare power toothbrush on natural and restorative dental materials using carefully controlled experimental conditions simulating typical long-term product use of up to 2 years. A manual toothbrush of traditional design (Oral-B P35 Soft) served as a control in all studies. The first study investigated the abrasion of restorative materials by evaluating changes in surface gloss and roughness of 2 commercially available composite materials (Solidex, EsthetX), surgical-grade titanium, and bovine enamel (control). The results demonstrated that the FlexCare is no more abrasive than a manual toothbrush on these materials. Any differences noted favored FlexCare over the manual brush at clinically relevant brushing load conditions. The second study compared wear of human dentin associated with the use of a manual toothbrush and 2 power toothbrushes. The results showed that in clinical loading conditions, FlexCare resulted in significantly less dentin abrasion than both the Oral-B Triumph Professional Care 9000 power toothbrush and the manual toothbrush. The third study assessed the effect of the FlexCare and a manual toothbrush on the bond strength of orthodontic brackets. No significant differences between treatments were found, suggesting that manual and sonic toothbrushes do not compromise orthodontic bond strength. In conclusion, these results indicate that the FlexCare power toothbrush does not compromise the longevity and appearance of natural and restorative dental materials or appliances compared with a manual toothbrush. These findings support the overall safety record of sonic toothbrushes for use in daily oral hygiene routines.



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Toothbrushing with toothpaste is the most common daily oral hygiene routine, frequently augmented with flossing and mouth rinses. Although the clinical efficacy of these treatments has been demonstrated repeatedly, relatively few studies have addressed the longer-term effect of toothbrushing and toothpaste on restorative oral surfaces and appliances. Consequently, dental professionals, as well as individuals who have undergone restorative dental procedures, such as veneers and crowns or implant placement, or those with orthodontic appliances should be concerned with the safety and efficacy of oral hygiene products on these surfaces. Although toothbrushes alone have little effect on dental hard tissues, damage to restorative materials as well as to dentin and, to a far lesser extent, enamel may result from the abrasiveness of toothpaste when used concurrently with a toothbrush.<sup>1</sup> Because earlier studies have shown that toothpaste abrasion may depend on the toothbrush used,<sup>2,3</sup> an investigation into the abrasive potential of any new toothbrush may be warranted.

The surface characteristics (in particular, roughness) of natural and restorative surfaces are of clinical and cosmetic relevance,<sup>4</sup> because a rougher surface facilitates adherence of dental plaque, stains, and calculus,<sup>5</sup> potentially leading to secondary caries and periodontitis.<sup>6</sup> Thus, the surface finish of restorations influences

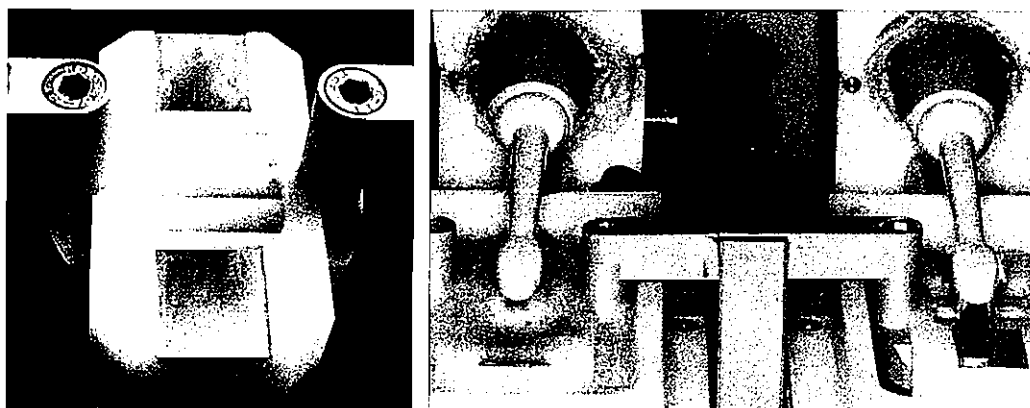


Figure 1—Dentin samples embedded into the mold and fixed in the specimen holder (left) and exposed to the toothbrush placed on top of the specimen—shown with and without toothpaste slurry for FlexCare (right)

their longevity.<sup>7</sup> Further, a rougher surface has less gloss, which affects its esthetic appearance. Smooth surfaces are more comfortable, because even a small change in surface roughness (about 0.3  $\mu\text{m}$ ) can already be detected by the tip of the tongue.<sup>9</sup> Abrasion of exposed dentin is an esthetic concern and is associated with increased hypersensitivity and root caries.<sup>10</sup>

Neme and colleagues,<sup>7</sup> citing Goldstein and Garber,<sup>11</sup> stated that a high percentage of restorations are compromised by the lack of ongoing maintenance by both patients and dental professionals. According to Teixeira and colleagues,<sup>8</sup> toothbrush abrasion is the main cause of material loss encountered by restorations in nonstress locations. Meiers<sup>12</sup> postulated that toothbrush design and toothpaste composition may be the most important factors in restorative surface degradation, particularly for users who are meticulous with their daily oral hygiene. Because of the plethora of manual toothbrush designs, power toothbrush motions, and toothpaste formulations, research into their effects on restorative surface integrity is warranted.<sup>12</sup> Few studies have investigated the care and maintenance of restorations related to professional and daily oral hygiene routines, other than survival rate after years of use.<sup>13</sup>

Power toothbrushes have been shown to be highly effective for patients with implants or orthodontic appliances.<sup>14-18</sup> Safety of power toothbrushes on orthodontic appliances and oral restorations has been evaluated in both in vitro<sup>19-22</sup> and clinical studies.<sup>13,15,17,18,23</sup>

Clinical studies have their limitations in establishing the safety of toothbrushes on natural and restorative surfaces, because safety analysis is typically limited to reporting immediately apparent

adverse events and cannot address slowly progressing wear of materials related to prolonged oral hygiene routines. In vitro tests, then, are preferred to establish first indications of clinical safety because they are more sensitive and flexible, allow greater experimental replication and standardization, and can realistically simulate long-term use in an accelerated manner. If warranted, in vivo tests can provide further evidence of safety during typical product use over extended periods.

This article summarizes 3 in vitro studies investigating the effect of the new Sonicare FlexCare<sup>®</sup> power toothbrush on natural and restorative dental materials using carefully controlled experimental conditions simulating typical long-term product use ranging from 6 months to 2 years. Materials included are human dentin, bovine enamel, esthetic restorative composites, implant grade titanium, and orthodontic brackets. A traditional design manual toothbrush was included as a control in all studies.

## Materials and Methods

### *Study 1: Restorative Materials Abrasion*

This laboratory investigation evaluated changes in surface gloss and roughness of 2 commercially available composite materials, surgical-grade titanium, and bovine enamel associated with the use of FlexCare power toothbrush with the ProResults radial brush head and a manual toothbrush (Oral-B P35 Soft<sup>®</sup>) as a control.

Four treatment groups and 4 test materials were involved in this study. The 4 treatment groups were the FlexCare power toothbrush at 100 g and the manual toothbrush at 250 g of brushing load, respec-

<sup>®</sup>Philips Oral Healthcare Inc; Snoqualmie, WA.

<sup>®</sup>Procter & Gamble Co; Cincinnati, OH.

tively, representing typical clinical use,<sup>1,2</sup> and 150 g for each brush used as a common reference point. The 4 materials were Solidex<sup>c</sup> composite, EsthetX<sup>d</sup> composite, 6AL-4V surgical-grade titanium, and bovine enamel, which served as the control for the composites.

Eight samples, each measuring 5 mm × 10 mm, were prepared for each of the 4 treatments. Solidex and EsthetX samples were constructed according to each manufacturer's recommendations. Enamel samples from adult bovine incisors were cut using a dental handpiece and a diamond-coated separating disk. Each sample was placed into an acrylic mount measuring 20 mm × 20 mm. To simulate tooth curvature at interproximal spaces, grooves measuring approximately 2 mm deep were placed parallel with a dental handpiece on either side of the material samples for the length of the acrylic mount. The acrylic mounts and the embedded composite, titanium, and enamel samples were then meticulously ground under water with a surface grinder resulting in uniformly polished surfaces. Finally, the top surface of each sample was hand polished to a high shine using a water slurry of 0.3 µm Alpha Alumina<sup>e</sup> and finishing with 0.05 µm Alpha Alumina on a cotton cloth. Specimens were randomly assigned to the 4 treatment groups.

Brushing was simulated by positioning the specimens on a V-8 mechanical cross-brushing machine<sup>25</sup> equipped with either the manual or the FlexCare power toothbrush. The power toothbrush handles were externally powered so that they would operate continuously at their normal setting during the complete brushing period without recharging. Specimens

were mounted below the toothbrush heads so the specimens were level with the toothbrush filament tip plane (defined by a plane between the tips of the filaments on the proximal and distal tufts). The mid-point of the stroke was aligned with the midpoint of the specimen to ensure even brushing conditions over the width of the specimen. Brushing force was controlled before the experiment. All specimens were assessed after 3,000 and 12,000 brushing strokes, representing 6 months and 2 years of brushing, respectively.<sup>1</sup> The brushing was done with a slurry consisting of 1 part (by mass) toothpaste (Crest Cavity Protection Cool Mint Gel<sup>®</sup>) to 2 parts (by mass) artificial saliva. Brush heads were immersed in the slurry using plastic tubes filled with the slurry placed around the free end of the brush head and specimen. Spoon-like attachments secured to the brush handles kept the slurry in suspension. Brushes and brush heads were replaced for each trial so that a new brush was used with each specimen.

Specimens were analyzed for abrasion by measuring both surface gloss and roughness induced by the different loads and brushes at baseline and 3,000 and 12,000 strokes. Gloss measurements were made with a Rhopoint Novo-Curve Glossmeter<sup>1</sup>. The mounted specimens were inverted on the Glossmeter platform parallel to and covering the 4-mm × 10-mm opening. Readings were taken at an operating angle of 60 degrees over the area covered by the aperture on top of the instrument. All readings are given in gloss units (GU) as specified in American Society for Testing and Materials (ASTM D523).<sup>26</sup> As a general rule, readings fall between zero (no reflectance) and 100 (highly reflective) for non-metallic surfaces. The calibration standard registers

<sup>c</sup>Shofu Dental Corp; San Marcos, CA.

<sup>d</sup>Dentsply Caulk; York, PA.

<sup>e</sup>Micropolish, Beuhler; Lake Bluff, IL.

<sup>1</sup>Rhopoint Instrumentation Ltd; Bexhill-on-Sea, UK.

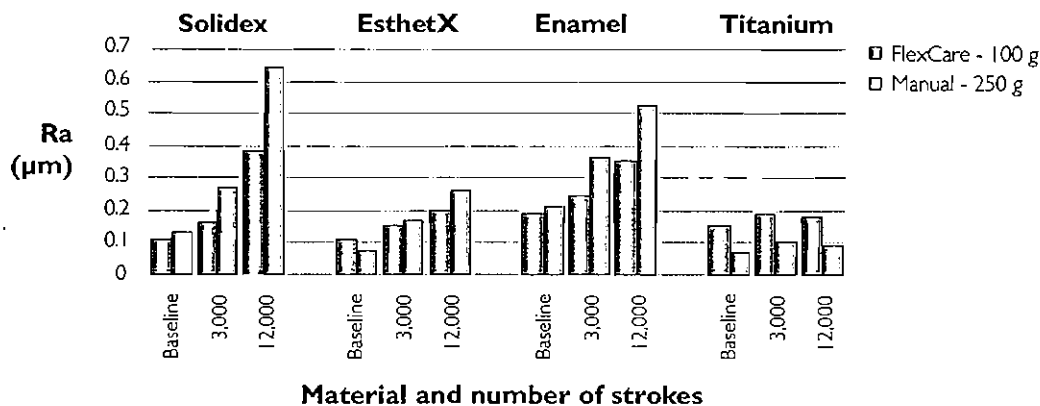


Figure 2—Change in surface roughness per material from baseline to 3,000 and 12,000 strokes for each treatment under clinical load conditions

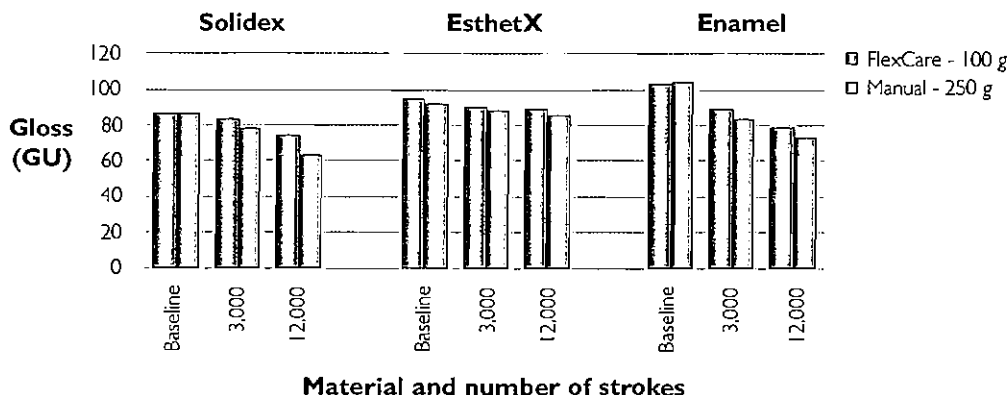


Figure 3—Change in surface gloss per material from baseline to 3,000 and 12,000 strokes for each treatment at clinical load conditions

at 94 GU. Roughness measurements were made through surface profilometry to assess the degree of damage (scratches). Roughness expressed as the Ra value is a direct measurement of surface roughness: smooth surfaces have a low Ra value and rough surfaces a higher one.

Statistical significance of differences between treatments for each material was determined by analysis of variance (ANOVA), and intergroup comparisons were made by means of the Student-Neuman-Keuls (SNK) test. Level of significance was set at  $P = .05$ . All SNK comparisons were made using a 2-tailed test.

#### Study 2: Dentin Abrasion

This study compared wear of human dentin associated with the use of a manual toothbrush and 2 power toothbrushes in a controlled setting corresponding to clinical use conditions.

The primary treatment groups comprised 3 toothbrushes with brushing loads that were deemed typical for clinical use conditions<sup>1,24,27</sup>: FlexCare with ProResults radial brush head at a 90-g brushing load; Oral-B Triumph Professional Care 9000<sup>b</sup> with FlossAction brush head at 150 g; and Oral-B P35 Soft manual toothbrush at 250 g. Two additional treatment groups, FlexCare and manual brush both at a 150-g brushing load, were included to allow a secondary comparison between the 3 toothbrushes for equal loads.

Dentin samples were taken from extracted human teeth without caries or restorations in the plane of section. The teeth were sectioned with a low-speed diamond saw along the inciso-apical plane, avoiding the pulp canals or pulp chambers, to obtain dentin slices that were 2 mm thick, 3 mm wide, and 10 mm long. Samples with irregularities,

such as discolorations, were discarded. The dentin slices were embedded into a mold made from a self-curing material for temporary crown and bridge restorations (Figure 1). The specimens were sanded and finished using 400-, 600-, and finally 1,200-grit standard industrial classification paper to obtain similar surface characteristics. Specimens were assigned randomly to the experimental groups.

Brushing was simulated by mounting the specimens below the toothbrush heads so the specimens were at the same level as the toothbrush filament tip plane and the center of the brush head passed over the center of the specimens (Figure 1). The specimen holder fully supported the toothbrush head throughout the entire brushing cycle. Weight was added to simulate the brushing force as required for each brush group. The power toothbrushes were externally powered to guarantee constant conditions throughout the test. The brushing was done with a toothpaste slurry prepared from 1 part (by mass) toothpaste (Crest Cavity Protection Cool Mint Gel<sup>b</sup>) and 1 part (by mass) water. The slurry was placed in the test chamber so the specimens were totally covered with the slurry. Sedimentation was avoided because the specimen holder was moving below the toothbrush head in the slurry bath and mixed the slurry continuously with every stroke. Each specimen was tested with a new brush head. Specimens were exposed to 12,000 strokes in the presence of toothpaste slurry, mimicking 2 years of clinical use.

Specimens were analyzed before and after brushing to assess the loss of material from wear through surface analysis with 3-dimensional laser scanner triangulation to determine the average loss in height ( $\mu\text{m}$ ) for each sample. Statistical differ-

ences between treatments were calculated with ANOVA and the Tukey test with the level of significance set at  $P = .05$ . The primary comparison was for clinical load conditions and the secondary was for equal brushing force conditions (150 g).

### Study 3: Orthodontic Bracket Strength

This study assessed the effect of manual and power toothbrushes on the bond strength of orthodontic brackets. The experimental set-up was largely identical to a previous study.<sup>23</sup>

Four groups were included: control specimens with no toothbrush exposure plus 3 treatment groups comprising a toothbrush and simulated brushing load typical of clinical use<sup>24</sup>: FlexCare with ProResults radial brush head at a 100-g brushing load; FlexCare with ProResults brush head at 100 g; and Oral-B 35 Soft manual toothbrush at 250 g.

Forty-eight specimens were prepared using caries-free, unrestored extracted human teeth onto which conventional metal orthodontic brackets (Mini Dyna-Lock<sup>®</sup>) were bonded using a conventional orthodontic resin bonding system (Transbond<sup>®</sup>) following the manufacturer's recommended procedures. The nonbracketed half of the tooth was

<sup>23</sup>M Unitek; Monrovia, CA.

embedded in an acrylic temporary bridge resin to securely hold it within the brushing machine and the shear bond test machine. Twelve specimens were randomly assigned to each of the 4 treatment groups.

Brushing was simulated using a machine that moved the toothbrushes back and forth across the specimen so the bristles traveled over the bracket. Weight was added to the brush handle to simulate the brushing force required for each brush group. Exposure duration was 12,000 strokes, representing the equivalent of a 2-year exposure to 2 brushings per day.<sup>25</sup> Brushing was undertaken with a slurry consisting of 0.5 part (by mass) toothpaste (Crest Cavity Protection Cool Mint Gel<sup>®</sup>), 0.8 part (by mass) water, and 1 part (by mass) artificial saliva. The slurry was kept in suspension and delivered to the brush heads continuously to maintain a wet brush condition. New brushes or brush heads were used with each specimen. The control specimens were mounted in the machine and exposed to the slurry without brushing.

For specimen analysis, each specimen was rigidly mounted in an Instron Universal Testing Machine<sup>b</sup>, and the shear force applied to the bracket until it broke free from the tooth surface was recorded.

<sup>b</sup>Instron Corp; Canton, MA.

Table 1—Average surface roughness (Ra) at baseline and increase from baseline after 3,000 and 12,000 brush strokes (N = 8; means  $\pm$  standard deviation)

Brush	Brushing load (g)	Baseline ( $\mu\text{m}$ )	Increase after 3,000 strokes ( $\mu\text{m}$ )	Increase after 12,000 strokes ( $\mu\text{m}$ )
<b>Solidex</b>				
FlexCare	100	0.11 $\pm$ 0.02 <sup>a</sup>	0.05 $\pm$ 0.02 <sup>a</sup>	0.27 $\pm$ 0.07 <sup>a</sup>
FlexCare	150	0.18 $\pm$ 0.07 <sup>a</sup>	0.09 $\pm$ 0.08 <sup>a</sup>	0.35 $\pm$ 0.16 <sup>a</sup>
Manual	150	0.16 $\pm$ 0.04 <sup>a</sup>	0.08 $\pm$ 0.04 <sup>a</sup>	0.29 $\pm$ 0.10 <sup>a</sup>
Manual	250	0.13 $\pm$ 0.06 <sup>a</sup>	0.14 $\pm$ 0.05 <sup>b</sup>	0.51 $\pm$ 0.15 <sup>b</sup>
<b>EsthetX</b>				
FlexCare	100	0.11 $\pm$ 0.06 <sup>a</sup>	0.04 $\pm$ 0.03 <sup>a</sup>	0.09 $\pm$ 0.05 <sup>a</sup>
FlexCare	150	0.13 $\pm$ 0.04 <sup>a</sup>	0.05 $\pm$ 0.03 <sup>a</sup>	0.10 $\pm$ 0.11 <sup>a</sup>
Manual	150	0.12 $\pm$ 0.07 <sup>a</sup>	0.05 $\pm$ 0.03 <sup>a</sup>	0.11 $\pm$ 0.03 <sup>a</sup>
Manual	250	0.08 $\pm$ 0.04 <sup>a</sup>	0.09 $\pm$ 0.09 <sup>a</sup>	0.18 $\pm$ 0.12 <sup>a</sup>
<b>Titanium</b>				
FlexCare	100	0.15 $\pm$ 0.03 <sup>AB</sup>	0.04 $\pm$ 0.04 <sup>a</sup>	0.03 $\pm$ 0.05 <sup>a</sup>
FlexCare	150	0.11 $\pm$ 0.06 <sup>AC</sup>	0.03 $\pm$ 0.02 <sup>a</sup>	0.00 $\pm$ 0.03 <sup>a</sup>
Manual	150	0.20 $\pm$ 0.06 <sup>a</sup>	0.02 $\pm$ 0.08 <sup>a</sup>	0.03 $\pm$ 0.05 <sup>a</sup>
Manual	250	0.07 $\pm$ 0.04 <sup>c</sup>	0.03 $\pm$ 0.04 <sup>a</sup>	0.02 $\pm$ 0.02 <sup>a</sup>
<b>Bovine enamel</b>				
FlexCare	100	0.19 $\pm$ 0.10 <sup>a</sup>	0.05 $\pm$ 0.06 <sup>a</sup>	0.16 $\pm$ 0.07 <sup>a</sup>
FlexCare	150	0.23 $\pm$ 0.08 <sup>a</sup>	0.09 $\pm$ 0.04 <sup>a</sup>	0.17 $\pm$ 0.28 <sup>a</sup>
Manual	150	0.23 $\pm$ 0.15 <sup>a</sup>	0.08 $\pm$ 0.09 <sup>a</sup>	0.16 $\pm$ 0.13 <sup>a</sup>
Manual	250	0.21 $\pm$ 0.08 <sup>a</sup>	0.15 $\pm$ 0.07 <sup>a</sup>	0.31 $\pm$ 0.51 <sup>a</sup>

For each variable, group values with a different letter are statistically different at  $P < .05$ . Values with the same letter are not statistically different from each other.

Table 2—Gloss measurements (GU) at baseline and decrease from baseline after 3,000 and 12,000 brushing strokes (N = 8; means  $\pm$  standard deviation)

Brush	Brushing load (g)	Baseline (GU)	Decrease after 3,000 strokes (GU)	Decrease after 12,000 strokes (GU)
<b>Solidex</b>				
FlexCare	100	85.4 $\pm$ 0.8 <sup>A</sup>	-2.2 $\pm$ 1.3 <sup>A</sup>	-11.3 $\pm$ 3.3 <sup>A</sup>
FlexCare	150	84.1 $\pm$ 1.8 <sup>A</sup>	-7.8 $\pm$ 5.7 <sup>B</sup>	-17.7 $\pm$ 3.0 <sup>B</sup>
Manual	150	84.8 $\pm$ 0.9 <sup>A</sup>	-2.6 $\pm$ 1.4 <sup>A</sup>	-15.6 $\pm$ 2.5 <sup>B</sup>
Manual	250	85.0 $\pm$ 1.0 <sup>A</sup>	-8.3 $\pm$ 0.9 <sup>B</sup>	-22.4 $\pm$ 3.9 <sup>C</sup>
<b>EsthetX</b>				
FlexCare	100	93.6 $\pm$ 1.8 <sup>A</sup>	-4.0 $\pm$ 2.2 <sup>A</sup>	-4.96 $\pm$ 2.3 <sup>A</sup>
FlexCare	150	93.2 $\pm$ 2.8 <sup>A</sup>	-4.2 $\pm$ 1.5 <sup>A</sup>	-6.79 $\pm$ 2.0 <sup>A</sup>
Manual	150	93.8 $\pm$ 2.1 <sup>A</sup>	-4.6 $\pm$ 2.9 <sup>A</sup>	-6.88 $\pm$ 2.7 <sup>A</sup>
Manual	250	92.1 $\pm$ 3.5 <sup>A</sup>	-4.4 $\pm$ 1.7 <sup>A</sup>	-7.65 $\pm$ 1.9 <sup>A</sup>
<b>Bovine enamel</b>				
FlexCare	100	101.6 $\pm$ 3.7 <sup>A</sup>	-12.9 $\pm$ 4.0 <sup>A</sup>	-23.3 $\pm$ 5.5 <sup>A</sup>
FlexCare	150	102.4 $\pm$ 2.5 <sup>A</sup>	-16.8 $\pm$ 1.7 <sup>B</sup>	-27.2 $\pm$ 2.7 <sup>AB</sup>
Manual	150	102.8 $\pm$ 2.3 <sup>A</sup>	-18.6 $\pm$ 3.6 <sup>B</sup>	-25.6 $\pm$ 5.8 <sup>AB</sup>
Manual	250	102.9 $\pm$ 3.8 <sup>A</sup>	-20.1 $\pm$ 1.9 <sup>B</sup>	-30.4 $\pm$ 2.9 <sup>B</sup>

For each variable, group values with a different letter are statistically different at  $P < .05$ . Values with the same letter are not statistically different from each other.

Statistical analysis was done through ANOVA, and the level of significance was set at  $P = .05$ , with shear force as the dependent variable and treatment group as the independent variable.

## Results

### Study 1: Restorative Materials Abrasion

**Roughness.** Table 1 presents the average roughness in micrometers for both brushes and their respective brushing loads at baseline and the increase after 3,000 and 12,000 brushing strokes for all 4 materials. Baseline data showed no significant differences between treatments for Solidex, EsthetX, and enamel. For titanium, baseline values were significantly different, which may reflect difficulties in obtaining an even surface for this relatively hard material. The more meaningful data are the changes from baseline, showing generally only small and nonsignificant differences between the 4 treatment arms, except for Solidex, where the manual brush at 250 g was statistically more abrasive than the other 3 treatment groups. Titanium experienced the smallest increase in roughness of all tested materials. EsthetX was more wear-resistant than Solidex and bovine enamel. Roughness increased from 3,000 to 12,000 strokes, except for titanium (Figure 2). Regardless of the toothbrush used, roughness increased with increasing loads.

**Gloss.** Table 2 presents the gloss measurements in GU for both brushes and their brushing loads for the 2 composites and enamel at baseline, and the

decrease from baseline after 3,000 and 12,000 strokes. Titanium was excluded, as gloss retention is not relevant for its use as a dental material. At baseline, gloss was well balanced and with no significant differences between treatments. Initial gloss was highest for enamel (about 102 GU) and lowest for Solidex (about 85 GU). As brushing time increased, gloss decreased continuously (Figure 3). For Solidex, there were statistically significant differences after 3,000 and 12,000 strokes, so that FlexCare at 100 g retained significantly more luster than the other 3 treatments, whereas the manual brush at 250 g had lost significantly more gloss than the other treatments. For EsthetX, reduction in gloss was less than for Solidex, with no significant differences between the 4 treatments. For bovine enamel, reduction in gloss was more pronounced compared with the composites and significantly larger for the manual brush at 250 g compared with FlexCare at 100 g. As with abrasion, gloss reduction increased from 3,000 to 12,000 strokes and with increasing loads, regardless of the toothbrush used.

The results of this study demonstrate that the FlexCare is no more abrasive than a manual toothbrush on restorative dental materials. If differences were noted, they favored the FlexCare over the manual brush at clinically relevant brushing load conditions (100 and 250 g, respectively; Figures 2 and 3). Within the limits of this study, it can be concluded that the Sonicare FlexCare is gentle on restorative materials.

### Study 2: Dentin Abrasion

Tables 3 and 4 and Figure 4 show the results of this study. In clinical loading conditions, FlexCare resulted in significantly less dentin abrasion ( $38\text{ }\mu\text{m}$ ) than both the Triumph ( $81\text{ }\mu\text{m}$ ) and the manual toothbrush ( $77\text{ }\mu\text{m}$ ). No significant differences were found between the Triumph and the manual toothbrush. Under uniform loading conditions ( $150\text{ g}$ ), FlexCare still showed the least abrasion, although the difference with the manual brush did not reach statistical significance. Both FlexCare ( $39\text{ }\mu\text{m}$ ) and the manual brush ( $51\text{ }\mu\text{m}$ ) resulted in significantly less dentin abrasion than the Triumph ( $81\text{ }\mu\text{m}$ ).

### Study 3: Orthodontic Bracket Strength

Table 5 shows the mean strength and standard deviation required to remove an orthodontic bracket from the specimens in each treatment group. Forty-seven specimens completed the testing; one specimen was excluded because of possible damage during handling. No significant differences between treatments were found. The results of this *in vitro* study simulating clinical use conditions suggest that toothbrush and toothpaste usage does not compromise orthodontic bond strength.

## Discussion

### Study 1: Restorative Materials Abrasion

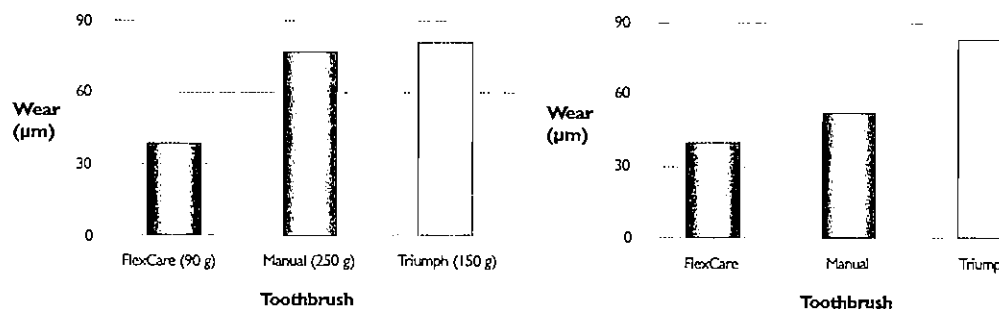
The first *in vitro* study compared the FlexCare and a manual toothbrush to determine their effect on changes in surface characteristics of 3 restorative materials (Solidex, EsthetX, and titanium) and bovine enamel. Surface changes were assessed for roughness and gloss. Scratches from brushing with a toothpaste increase roughness and decrease gloss concurrently. To our knowledge, this is the first report on a comprehensive evaluation related to power toothbrushes. Increase in roughness and loss

in luster of dental materials after prolonged use of oral hygiene procedures appears inevitable, requiring refinishing of restorations at times. In this study, baseline readings resulted from meticulous polishing using alumina, possibly resulting in a smoother polish than would typically be obtained from in-office treatment. Regardless, the question was whether the Sonicare FlexCare power toothbrush would differ from a manual brush, and the data suggest that when differences were observed, they favored the FlexCare. In practice, it may be postulated that over extended periods of time, changes in surface characteristics will level off to a polishing range determined by the toothpaste abrasive and wear resistance of the specific material, regardless of the toothbrush used. Indeed, a preliminary study on Solidex with additional assessments at 1,500, 6,000, and 24,000 brushing strokes showed a nonlinear change and leveling off between 12,000 and 24,000 strokes (data not shown). Nonetheless, this current study suggests that for clinical loading conditions, abrasion with the FlexCare progresses slower compared with the manual brush using a higher brushing force, and might, therefore, require less professional repolishing of restorations.

### Study 2: Dentin Abrasion

The second *in vitro* study compared dentin abrasion in simulated clinical conditions for the FlexCare with an oscillating-rotating power toothbrush and a manual toothbrush and showed that the FlexCare was significantly less abrasive than the other 2 brushes. Under equal brushing loads, FlexCare still resulted in less abrasion than the other brushes. These results are consistent with similar experiments for previous Sonicare model, which indicated that Sonicare brushes result in significantly less dentin abrasion than manual toothbrushes and oscillating-rotating power toothbrushes.<sup>33</sup>

Figure 4—Abrasion of dentin samples after 2 years of simulated brushing with toothpaste



A. Clinically relevant brushing forces

B. Equal (150 g) brushing forces

**Table 3—Wear of dentin samples after 2 years of simulated brushing with toothpaste using clinically relevant brushing forces**

Brush	Brushing load (g)	Sample size	Average wear (µm)	Standard deviation (µm)	Significance (P < .05)
FlexCare	90	12	37.8	14.9	A
Triumph	150	12	80.9	42.7	B
Manual	250	16	77.4	27.3	B

Treatment values with a different letter are statistically different at  $P < .05$ . Values with the same letter are not statistically different from each other.

**Table 4—Wear of dentin samples after 2 years of simulated brushing with toothpaste using equal brushing forces (150 g) for all brushes**

Brush	Sample size	Average wear (µm)	Standard deviation (µm)	Significance (P < .05)
FlexCare	12	38.6	14.4	A
Triumph	12	80.9	42.7	B
Manual	12	50.9	16.7	A

Treatment values with a different letter are statistically different at  $P < .05$ . Values with the same letter are not statistically different from each other.

**Table 5—In vitro shear bond strength of orthodontic brackets after 2-year exposure to treatment**

Treatment	Sample size	Shear bond strength		
		Mean (N)	Standard Deviation (N)	
Control (no treatment)	12	107.70	38.84	A
Manual	11	98.15	28.24	A
FlexCare with ProResults radial brush head	12	77.61	20.57	A
FlexCare with prototype brush head	12	87.50	13.15	A

Treatment values with the same letter are not statistically different from each other. They are the same at  $P < .05$ .

### Study 3: Orthodontic Bracket Strength

The third in vitro study compared the effect of the FlexCare power toothbrush and a manual toothbrush on orthodontic bracket retention strength. The results indicated that there were no significant differences between the 2 brushes, suggesting that both manual and power toothbrushes are safe to use in orthodontic patients. This would confirm previous clinical results that have shown that power toothbrushes do not affect the survival of orthodontic brackets.<sup>23</sup> These results are also consistent with in vitro studies showing no significant effect of manual and sonic toothbrushes on tensile bond strength of cemented crowns and restorations.<sup>19,22,28</sup>

Although it has been postulated that toothbrush design and toothpaste composition may be the most important factor in restorative surface degradation,<sup>12</sup> some limitations exist with current in vitro studies. Although the slurry used approximated the oral chemistry during toothbrushing, food consumption and other oral environmental conditions were not tested. Apart from these environmental effects, the mechanical effects of clinical toothbrush abrasion were adequately represented in current in vitro stud-

ies. These abrasive effects depend on usage factors, including manual dexterity, brushing force, brushing time, and toothbrush and toothpaste used. In current studies, brush type and their respective clinical load conditions were the only variables assessed, while brushing motion (back-and-forth strokes), the number of strokes, and toothpaste slurry were normalized within each study to evaluate comparative effects of the selected toothbrushes. Because abrasion mechanisms may be influenced by the interaction of mechanical, chemical, and biological processes, clinical trials would provide further assessments.<sup>8</sup>

### Conclusion

In summary, the results of the current studies and cited literature provide in vitro evidence of the safety of power toothbrushes on natural and restorative dental materials and orthodontic brackets and suggest similar results may be obtained from a long-term longitudinal clinical study. These results indicate that the Sonicare FlexCare toothbrush does not compromise the longevity and appearance of natural and restorative dental materials and appliances compared with similar effects observed with a manual

toothbrush. These findings add weight to the overall safety record of sonic toothbrushes for use in daily oral hygiene routines.

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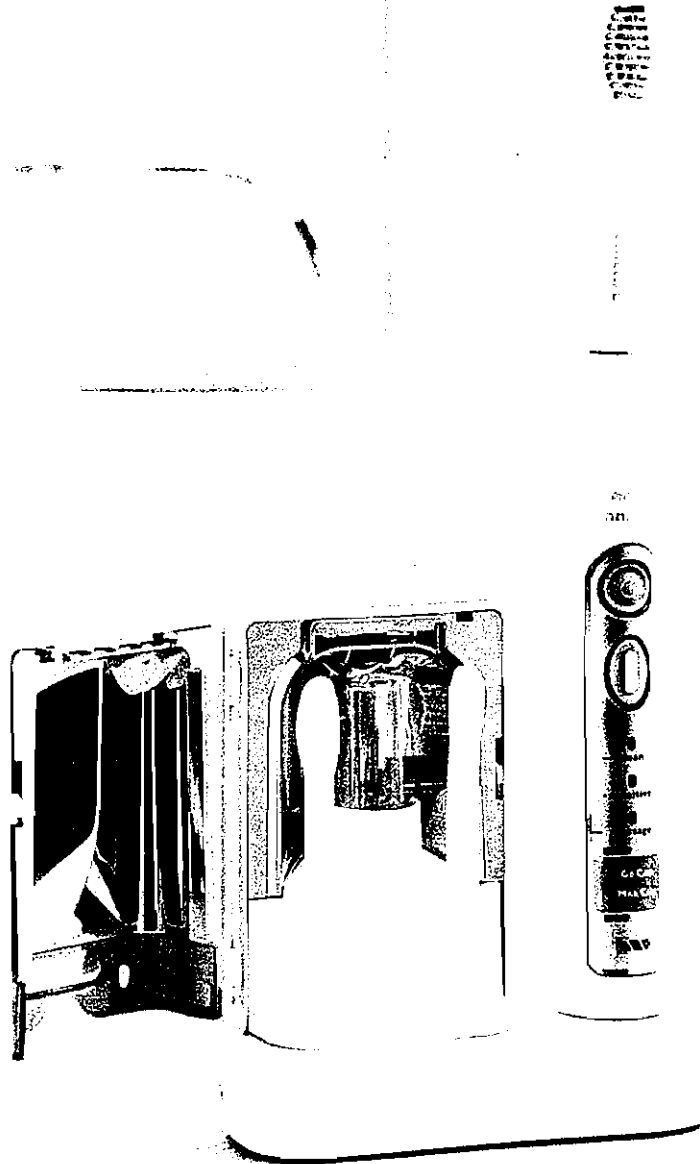
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